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Advancing Antipsychotic Therapy: Clinical Utility of Aripiprazole Oral Solution

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ABSTRACT

Antipsychotic therapy remains central to the management of schizophrenia and related disorders; however, treatment adherence is a persistent clinical challenge due to side effects, complex regimens, and swallowing difficulties. Aripiprazole, a dopamine D2 and serotonin 5-HT1a partial agonist with 5-HT2a antagonistic properties, is recognized for its broad therapeutic utility and favourable tolerability profile across schizophrenia, bipolar disorder, and major depressive disorder. The oral solution formulation of aripiprazole represents a clinically meaningful advancement aimed at improving compliance and administration flexibility. Dysphagia, prevalent among elderly and institutionalized patients, often leads to unsafe practices such as tablet crushing or mixing with food, potentially altering bioavailability and dosing accuracy. By providing a ready-to-use, palatable oral option, aripiprazole oral solution mitigates these risks and supports consistent medication use. Additionally, in acute psychiatric settings, oral solution formulations enable rapid and cooperative administration, offering a patient-centred alternative to parenteral routes while preserving the therapeutic alliance. Evidence demonstrates comparable efficacy, safety, and pharmacokinetic profiles between oral solution and tablet formulations. As a value-added medicine, aripiprazole oral solution addresses practical barriers to adherence, improves patient outcomes, and offers a cost-effective strategy aligned with modern, individualized psychiatric care.

Keywords: Aripiprazole*;* Antipsychotic Agents*;* Oral Aripiprazole; Medication Adherence*;* Patient Compliance*;* Deglutition Disorders.

INTRODUCTION

Antipsychotic medications remain the cornerstone of treatment for schizophrenia and related disorders, with additional roles in bipolar disorder and as adjunctive therapy for major depressive disorder (MDD) [1]. Successful pharmacotherapy depends not only on drug efficacy but also on sustained adherence. Treatment choice is influenced by previous response, tolerability, and patient preferences, including formulation type. Non-response or adverse effects often lead to therapy changes, with up to 50% of outpatients switching between atypical antipsychotics each year [2]. However, before considering a treatment ineffective, adherence must be evaluated, as non-compliance - affecting 40–50% of individuals with schizophrenia - contributes substantially to relapse, persistent symptoms, and higher healthcare costs [3].

To address adherence barriers, various antipsychotic formulations have been developed. Oral agents remain first-line, while intramuscular (IM) and depot formulations are used for acute agitation or maintenance in poorly adherent patients [4]. Rapidly disintegrating tablets and oral solution facilitate easier administration and allow direct observation of dosing, improving compliance [5]. Despite these advantages, oral solutions of antipsychotics are underutilized, though particularly valuable for patients with dysphagia, agitation, or uncertain adherence [6, 7]. The aripiprazole oral solution exemplifies a value-added innovation—maintaining the efficacy and safety of the tablet form while enhancing flexibility, tolerability, and adherence. By minimizing medication manipulation and supporting consistent use, such formulations represent a cost-effective, patient-centred advancement in psychiatric care [8].

Aripiprazole

Aripiprazole is an atypical antipsychotic that has been approved for the treatment of schizophrenia, bipolar I disorder, and irritability associated with autism spectrum disorder (ASD). It is used as monotherapy or adjunctive therapy for acute manic and mixed episodes in bipolar I disorder and as maintenance therapy for chronic schizophrenia. Both oral tablet and oral solution forms are USFDA-

approved for reducing irritability, hyperactivity, and repetitive behaviors in ASD. Additionally, aripiprazole is indicated as adjunctive treatment for MDD and for managing Tourette syndrome. The long-acting injectable formulation offers a valuable option for patients who have difficulty maintaining adherence to oral medication or who experience intolerance to other antipsychotic agents [9, 10].

Beyond its approved uses, aripiprazole has shown promise in several neuropsychiatric and neurodevelopmental disorders. In children and those with mild intellectual disability (ID), it helps manage aggression, tantrums, and self-injurious behaviour through partial agonism at dopamine D_2 and serotonin 5-HT_{1a} receptors and antagonism at 5-HT_{2a} receptors, improving behavioural control with fewer extrapyramidal effects (EPS). Off-label, aripiprazole is also used for behavioural and psychological symptoms of dementia (BPSD) such as agitation and psychosis, particularly when non-pharmacological strategies fail. Clinical studies in Alzheimer's and other dementias indicate modest improvements, though there remains some risk of cerebrovascular events and cognitive decline. Its favourable safety and tolerability profile, including lower rates of metabolic and motor side effects, has also supported exploration in Parkinson's disease–related delirium, with emerging evidence suggesting additional benefits in cognitive function, metabolic health, and overall quality of life [11–14].

Mechanism of Action

Aripiprazole is a unique atypical antipsychotic acting as a **partial agonist at dopamine D_2 and serotonin 5-HT_{1a} receptors** and an **antagonist at 5-HT_{2a} receptors**. It has **high affinity for D_2, D_3, 5-HT_{1a}, and 5-HT_{2a} receptors** and moderate affinity for D_4, 5-HT_{2c}, 5-HT_7, α_1-adrenergic, and H_1 receptors, with no significant activity at muscarinic receptors. By **stabilizing dopamine and serotonin activity** in the nucleus accumbens, ventral tegmental area, and frontal cortex, it effectively treats **positive, negative, and cognitive symptoms** of schizophrenia. Its **functional selectivity** allows clinical efficacy at high D_2 receptor occupancy (>90%) while minimizing EPS. Acting as a **functional antagonist** in dopamine-rich mesolimbic areas and inactive in nigrostriatal regions, it balances dopamine signaling more precisely than haloperidol or olanzapine. This **selective modulation** contributes to its lower risk of motor and endocrine side effects, though combining it with other antipsychotics may worsen positive symptoms due to its partial agonist nature [15–19].

Dosage and Administration

Aripiprazole can be taken with or without food and is available as oral tablets, orally disintegrating tablets, oral solution, and IM injections, both short- and long-acting. Typical oral doses range from 5–30 mg/day, with tablets available in multiple strengths. The oral form has a long half-life of about 75 hours, reaching steady-state levels in roughly two weeks. Long-acting IM injections achieve peak plasma levels within 5–7 days, and the depot formulation (300 or 400 mg) is administered monthly, offering an effective option for patients with adherence difficulties. Before switching to IM therapy, oral tolerability should be established, with oral dosing continued for 14 days during the transition. [15]

For schizophrenia, the recommended oral dose is 10–15 mg/day, adjustable up to 30 mg/day. In bipolar I disorder, monotherapy typically starts at 15 mg/day and may increase to 30 mg/day. As adjunctive therapy in bipolar disorder or MDD, doses begin at 2–5 mg/day and can be titrated to 15 mg/day. No adjustment is needed in renal or hepatic impairment, though strong CYP3A4 inducers like carbamazepine may require dose increases [20].

Adverse Effects

Aripiprazole is generally well tolerated compared with other antipsychotics, showing a lower risk of EPS, metabolic disturbances, and prolactin elevation due to its receptor selectivity. Movement-related effects such as akathisia, tremor, or dystonia may occur but are usually mild and manageable. It is associated with less weight gain, dyslipidemia, glucose intolerance, and cardiovascular effects, with common adverse reactions including somnolence, nausea, restlessness, and dizziness.

Caution is advised in elderly patients, as antipsychotics may precipitate syndrome of inappropriate antidiuretic hormone secretion or hyponatremia; sodium levels should be monitored during initiation or dose changes. Children and adolescents are more susceptible to EPS and metabolic effects. Rare but serious events include neuroleptic malignant syndrome, hepatic dysfunction, seizures, and agranulocytosis. Aripiprazole carries boxed warnings for increased cerebrovascular risk and mortality in elderly patients with dementia-related psychosis, and for suicidal ideation in younger individuals [13, 21].

Added Value of Aripiprazole Oral Solution: Utility in Special Conditions and Subpopulations

Aripiprazole oral solution represents a significant advancement in antipsychotic formulation technology, addressing several practical and clinical challenges associated with tablet-based therapy. One of its primary advantages is improved ease of

administration, particularly in patients with dysphagia, a condition affecting up to 70% of elderly, psychiatric, and institutionalized populations. For these individuals, swallowing tablets can lead to poor adherence or unsafe practices such as crushing tablets or mixing them with food or beverages - behaviors that may alter pharmacokinetic properties and compromise therapeutic efficacy. The ready-to-use oral solution formulation eliminates the need for such manipulation, ensuring accurate dosing and consistent bioavailability [22].

Another key advantage is enhanced treatment adherence and flexibility. The oral solution allows for precise dose titration, facilitating gradual adjustments according to patient response and tolerability. Its ease of ingestion improves compliance among populations who have difficulty swallowing or are resistant to taking solid oral medications, including pediatric, geriatric, and acutely psychotic patients. In supervised care or inpatient settings, oral solution formulations also enable direct observation of administration, reducing the risk of covert non-adherence.

In acute psychiatric or emergency settings, where patients may be agitated or uncooperative, the aripiprazole oral solution offers a less invasive and more acceptable alternative to IM injections. It allows for rapid and cooperative administration while maintaining the therapeutic alliance between clinician and patient. Additionally, its comparable efficacy and safety to the tablet formulation have been confirmed in clinical evaluations, supporting its reliability as an interchangeable option [23].

From a health-system perspective, aripiprazole oral solution provides a cost-effective, value-added option that enhances convenience, safety, and adherence—factors directly linked to reduced relapse rates, fewer hospitalizations, and improved long-term outcomes. By addressing real-world barriers to medication adherence, the aripiprazole oral solution exemplifies a patient-centred approach to optimizing psychiatric pharmacotherapy [7].

Swallowing Difficulties: Need for Proper Management

Age-related physiological changes, comorbidities, and the effects of certain medications can impair neural and muscular coordination required for swallowing, making dysphagia a common concern among older adults. Swallowing difficulties affect roughly one-third of people at some point in life, increasing to 10–35% in adults over 65 and up to 70% among nursing home residents [22, 24]. Many elderly individuals experience selective difficulty swallowing solid oral medications despite tolerating food and liquids. Approximately 25–50% report discomfort with tablets or capsules, and factors such as large size, surface texture, or unpleasant taste can discourage adherence. Among those affected, 4% discontinue therapy entirely, 10–14% delay or skip doses [25], and up to 70% admit to missing medication because of swallowing issues [26].

Dysphagia in Schizophrenia and Antipsychotic-Induced Dysphagia

Dysphagia occurs in about 23% of schizophrenia inpatients and is often underrecognized. Both disease-related behavioural symptoms and antipsychotic medications can impair swallowing function [27]. Typical and atypical antipsychotics - particularly haloperidol and risperidone - have been associated with oropharyngeal dysphagia, primarily through EPS, with additional contributions from dry mouth and sedation [28]. Management includes switching to agents with lower EPS risk, such as aripiprazole, olanzapine, or quetiapine, and addressing xerostomia with artificial saliva or moisture-stimulating foods [22]. Because sedative effects can further suppress the swallowing reflex - especially when antipsychotics are combined with benzodiazepines or other sedatives - minimizing polypharmacy is essential [29, 30].

Antipsychotic Oral Solution or Coping Strategies for Swallowing Issues

Swallowing difficulties should ideally be evaluated and managed appropriately. When possible, treating the underlying cause and excluding drug-induced dysphagia is preferred. However, such issues are often underreported, leading patients and caregivers to adopt self-initiated coping strategies such as tablet crushing, splitting, mixing with food, or omitting doses [25]. These practices can be unsafe and affect drug efficacy or safety. In such cases, oral solution formulations offer a practical and cost-effective alternative; otherwise, alternative administration routes should be considered.

Oral Solutions of Antipsychotic in Dementia Care

In patients with dementia, **oral solution formulations,** provide important **administration benefits** by overcoming difficulties related to dysphagia, cognitive decline, and medication nonadherence. Oral solution formulations are easier to swallow, allow for **accurate dose titration**, and are better tolerated than tablets or injections, thereby enhancing safety and treatment consistency. Their **non-invasive** nature reduces distress and aspiration risk, while also improving caregiver convenience and patient comfort. These features make oral solutions a practical option for managing behavioural and psychological symptoms of dementia, though their use should remain cautious due to the increased mortality and cerebrovascular risks associated with antipsychotic therapy [43, 44].

Overcoming Dosing Barriers in Children with Autism with Oral Solutions

Children with ASD often face major challenges with medication administration due to sensory sensitivities, rigid routines, and aversions to certain tastes or textures, making tablets difficult to swallow. Communication barriers and behavioural resistance can further complicate dosing, while feeding difficulties and motor issues increase the risk of choking with solid forms. In such cases, **oral solution of antipsychotic**, offers clear advantages as they are easier to swallow, allow precise dose adjustments, and can be flavoured to improve acceptance. These benefits enhance adherence, reduce anxiety during administration, and give caregivers better control, resulting in more consistent and effective treatment in children with ASD [45].

Omitting Antipsychotic Treatment

Treatment omission is notably higher among patients with swallowing difficulties (9.8% vs 2.9%) [31]. Abrupt discontinuation of antipsychotics may cause withdrawal syndromes, with aripiprazole withdrawal presenting as anxiety, panic attacks, or sweating [32]. Since aripiprazole oral solution is easier to swallow, it can improve adherence and reduce the risks of missed doses and withdrawal.

Altering Solid Oral Dosage Formulation

Altering oral solid formulations - such as crushing, splitting, or mixing pills with food or liquids - is a common coping strategy but can change drug pharmacokinetics and cause safety issues. These practices should only be used when no suitable alternatives exist [33]. Poor crushing methods may lead to inconsistent dosing, drug loss, or waste [34, 35]. Manipulating extended-release tablets can cause rapid absorption and toxicity [25]. While aripiprazole overdose usually causes mild sedation, other antipsychotics may lead to severe reactions like seizures or coma, especially in the elderly with slower drug clearance [36].

Crushing or altering coated tablets can create a bitter taste, reduce adherence, and impair absorption when mixed with food or drinks [34]. Surveys show that crushing or cutting tablets (26%) and mixing with food or liquids (13%) are frequent due to limited oral solution options. A cross-sectional study reported that nearly one-third of inpatients with severe mental illness received their medication mixed with food or drinks, mainly due to swallowing difficulties (62%) or refusal to take medication (47%) [33]. These practices are especially common in elderly psychiatric patients and significantly increase the risk of dosing errors and improper medication handling [30, 37, 38].

Oral Solution versus Oro-dispersible Antipsychotics in Patients with Swallowing Difficulties

Both solution and orodispersible antipsychotics are useful alternatives for patients with swallowing difficulties. Although systematic comparisons are limited, preliminary evidence suggests that oral solution formulations may offer easier administration [37]. Orodispersible tablets, though designed to dissolve quickly, are sometimes crushed - potentially affecting efficacy. An observational study in care-home residents showed that caregivers often handled orodispersible tablets like standard capsules, likely due to limited training [30]. While orodispersible tablets improve swallowing comfort and patient acceptance, studies indicate no significant difference in airway safety compared to conventional tablets [39, 40]. Conversely, oral solution formulations, especially thin liquids, may increase aspiration risk, which can be reduced by adjusting viscosity, controlling volume, and using proper swallowing techniques [41]. Despite the potential for dosing errors from inaccurate volume measurement, oral solution antipsychotics remain a practical and patient-friendly option for those unable to tolerate solid oral medications.

Agitated Patients with Schizophrenia or Bipolar Disorder

Episodes of agitation and aggression affect up to 90% of patients with schizophrenia or bipolar disorder and require prompt and effective management [42]. Treatment goals focus on rapid stabilization without excessive sedation, preserving the therapeutic relationship, minimizing restraint use, and ensuring follow-up care. Whenever possible, cooperative patients should be involved in choosing their medication and route of administration, with oral formulations - especially liquids or dispersible tablets - preferred over IM injections for mild agitation [23].

A systematic review of randomized controlled trials found no consistent evidence of superiority among pharmacologic treatments for agitation in schizophrenia or bipolar disorder. Most studies evaluated parenteral agents such as olanzapine, aripiprazole, haloperidol, risperidone, ziprasidone, and lorazepam [42]. Although IM antipsychotics are effective in emergencies and for uncooperative patients, their invasive and often involuntary use can undermine trust and damage the therapeutic alliance [7].

Oral solutions of antipsychotic present a less invasive and more acceptable alternative for cooperative, mildly agitated patients. They offer easy administration, fast onset of action and better adherence compared with tablets. Studies indicate that oral solution

formulations are as effective and well-tolerated as oral tablet and IM options [4]. Specifically, aripiprazole oral solution is a practical choice for mild agitation, providing short-term calming effects and supporting long-term adherence. With a lower risk of EPS and improved patient satisfaction, it may enhance compliance and facilitate ongoing maintenance therapy without unnecessary switching.

Conclusion

Aripiprazole oral solution has efficacy and safety comparable to the tablet formulation and is suitable for the same indications. It offers practical advantages in patients with poor adherence, swallowing difficulties, and in acute settings by enabling flexible, non-invasive administration and accurate dose titration. As a value-added medicine, it improves treatment continuity, supports individualized care, and provides a cost-effective option for optimizing outcomes in routine psychiatric practice.

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