

Regional Expert Opinion on Tolvaptan Therapy for ADPKD: Bridging Gaps in the GCC and MENA Regions

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Abstract

Autosomal Dominant Polycystic Kidney Disease (ADPKD) constitutes one of the most common hereditary renal disorders, characterized by progressive cystic enlargement and a subsequent decline in renal function. Although the condition presents a significant health burden in regions with high rates of consanguinity, such as the Gulf Cooperation Council (GCC) and the Middle East and North Africa (MENA), comprehensive regional data on its prevalence, diagnosis and management remain limited. Tolvaptan, a selective antagonist of the vasopressin V2 receptor, is presently the sole disease-modifying therapy approved for decelerating the progression of ADPKD. This review is based on the synthesis of current literature amalgamated with the opinions of nephrologists (from the Kingdom of Saudi Arabia, Kuwait, Oman, Bahrain and the United Arab Emirates) convened to develop guidance on the utilization of Tolvaptan in ADPKD across the GCC/MENA region. The panel underscored the significance of establishing national and regional registries, deploying standardized imaging and diagnostic protocols, expanding access to genetic testing and counseling and ensuring the safe administration of Tolvaptan during Ramadan fasting. This review aims to bridge the gap between evidence and clinical practice, providing a structured framework to guide clinicians, facilitate early diagnosis and enhance therapeutic approaches for ADPKD patients throughout the GCC and MENA regions.

Keywords: Autosomal dominant polycystic kidney disease • Expert opinion • Gulf cooperation council • Kidney disease • Improving global outcomes • Guidelines • Middle East and North Africa • Tolvaptan • Genetic testing

Introduction

Autosomal Dominant Polycystic Kidney Disease (ADPKD) is the most common hereditary cause of kidney failure globally, characterized by the development of cysts in the kidneys and liver, as well as an increased risk of intracranial aneurysms. This condition ultimately leads to renal dysfunction, culminating in End-Stage Kidney Disease (ESKD) and heightened dependence on renal replacement therapy [1]. The pain, fatigue, discomfort, impaired mobility and emotional distress associated with ADPKD substantially diminish patients' quality of life [2]. Tolvaptan, a Vasopressin (V2) receptor antagonist, is currently the only approved drug for ADPKD treatment. It works by decelerating cyst growth through depressing intracellular cyclic Adenosine MonoPhosphate (cAMP) levels via blocking vasopressin binding to V2 receptors in the kidney [3,4]. TEMPO 3:4 and REPRISÉ trials have demonstrated the effectiveness

of Tolvaptan in managing ADPKD. Approximately 43 countries, including the European Union, the United States, Australia, Japan, China, Canada and South Korea, have granted licenses and permits for its use in treating ADPKD [1,5,6]. Several studies indicate that ADPKD is more common in countries with high rates of consanguinity, like the GCC/MENA region [7-9].

Despite the availability of global evidences and clinical guidelines, the applicability of these recommendations in the GCC/MENA regions remain limited due to distinctive cultural, demographic, genetic and healthcare-system factors. In the absence of robust regional data and unified care pathways, expert-driven opinion can serve as an essential bridge between evidence and real world clinical practise. Therefore, this expert opinion review is aimed to synthesize current literature, regional experience and collective clinical judgement to provide guidance on the utilization of Tolvaptan in ADPKD across the GCC/MENA region.

Epidemiology of ADPKD

ADPKD is increasingly recognized as a significant global health concern, affecting around 15 million people globally and associated with a high risk of complications such as hypertension, kidney complications, ESKD, polycystic liver disease and intracerebral aneurysm rupture [10]. The disease impacts all races, with prevalence rates from 1:400 to 1:1,000 among diagnosed individuals [11]. One study highlighted that race and ethnicity significantly influence ADPKD prevalence, noting higher rates in non-Hispanic White and Black populations compared to Hispanic and Asian groups [12]. Moreover, regional differences in prevalence exist and the progression and response to treatment in ADPKD can be affected by genetic and ethnic factors [13,14].

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Diagnosis and risk stratification of ADPKD

A comprehensive approach is crucial for diagnosing, assessing and treating ADPKD, which may involve imaging, genetic testing and other specific tests as needed. Ultrasound imaging is the primary, safe, affordable and widely accessible method used initially, especially in those with a family history, to detect the number and location of cysts, particularly in older adults [15]. More advanced techniques, such as Magnetic Resonance Imaging (MRI) and Computed Tomography (CT), are primarily used for risk stratification and monitoring disease progression and complications in certain patients; they are not essential for all cases. These methods help measure Total Kidney Volume (TKV), which accurately and reproducibly indicates disease severity and progression, especially in early stages. The Mayo Imaging Classification (MIC) divides ADPKD patients into five categories (1A-1E) based on height-adjusted TKV (htTKV), predicting kidney outcomes [16]. Mutations in the PKD1 and PKD2 genes are responsible for over 90% of the ADPKD cases, with PKD1 mutations leading to a more rapid decline in renal function than PKD2 mutations. While not mandatory, genetic testing of these genes is often inaccessible and generally not required for diagnosis, but it can offer prognostic insights and can be useful in uncertain cases, for those with negative family history, for atypical presentations, for evaluating potential living donors, for family planning and for research [17]. For genetic analysis, Next-Generation Sequencing (NGS) is highly accurate, reliable, faster, cost-effective and superior to Sanger sequencing, offering greater sensitivity and broader gene coverage [18]. Targeted gene panels for PKD1 and PKD2 and Whole-Exome Sequencing (WES) both use Next-Generation Sequencing (NGS) technologies. WES focuses on the protein-coding regions of the genome and is useful for identifying variants in other ADPKD-related genes (such as GANAB and DNAJB11), particularly when initial targeted testing of PKD1 and PKD2 is negative [19,20].

Managing ADPKD with tolvaptan

Tolvaptan is prescribed and utilized as a long-term therapeutic intervention aimed at decelerating the progression of renal function decline in adult patients. The initiation and titration of Tolvaptan should be conducted with meticulous care to balance therapeutic efficacy against the risk of adverse effects. Typically, the recommended initial dose of Tolvaptan is 45 mg prior to the morning meal and 15 mg taken 8 hours later with or without food. Nonetheless, subject to patient tolerability and clinical response, the dosage may be increased incrementally monthly up to the maximum tolerated dose of 90/30 mg. A lower tolvaptan dose (15/15 mg or 30/15 mg) can be considered for patients who are highly sensitive to the effects of aquaresis, such as those with better baseline renal function or specific work-related lifestyle constraints (consistent with KDIGO and Mayo practice). Before starting Tolvaptan, all patients should be educated on the optimal diet, fluid intake and to drink enough water to prevent thirst [21,22]. Given the potential for drug-induced hepatotoxicity, routine monitoring of Liver Function Tests (LFTs) is a vital safety protocol for patients with ADPKD receiving Tolvaptan. These tests should include assessments of total bilirubin and specific liver enzymes, such as Alanine Amino Transferase (ALT) and aspartate aminotransferase (AST) [22]. In ADPKD, first-line therapy for hypertension is an Angiotensin-Converting Enzyme (ACE) inhibitor or Angiotensin II Receptor Blockers (ARB). The KDIGO 2025 guidelines do not recommend Sodium-Glucose Cotransporter 2 (SGLT2) inhibitors, GLP-1 Receptor Agonists (GLP-1 RAs) and Finerenones for slowing disease progression, as their benefits in ADPKD remain unproven.

Impact of ramadan fasting on ADPKD patients using tolvaptan

Fasting during Ramadan is a significant religious observance in the GCC and MENA regions, involving abstention from drink, food, smoking and medications during daylight hours. Although children, breastfeeding mothers, menstruating and pregnant women, elderly individuals, ill persons and travelers are exempt from this practice, many of these groups voluntarily observe fasting alongside their family members [23]. Notably, there is a considerable impact on patients with ADPKD who are receiving Tolvaptan and observing fasting during Ramadan. Manufacturers advise against using Tolvaptan in conditions of dehydration. Consequently, fasting is generally discouraged for patients

on Tolvaptan due to the substantial risk of dehydration. Tolvaptan increases aquaresis and thirst in patients with ADPKD, necessitating high daily fluid intake to prevent dangerous fluid imbalances. However, experts hold differing views on fasting in patients with ADPKD. Many prefer Ramadan fasting during the cold season, as it helps reduce the risk of dehydration [24,25].

Expert Opinion

A panel of regional experts in Autosomal Dominant Polycystic Kidney Disease (ADPKD) from the Kingdom of Saudi Arabia, Kuwait, Oman, Bahrain and the United Arab Emirates convened to discuss the current landscape of ADPKD management in the GCC and MENA regions. The discussion encompassed epidemiological insights into regional disease prevalence, evidence-based approaches to treatment initiation and optimization, strategies for monitoring and managing adverse events and the clinical assessment of Tolvaptan efficacy. The panel also proposed forward-looking recommendations to advance diagnostic precision, therapeutic strategy and overall management frameworks for ADPKD within the GCC/MENA context.

National and regional registries for ADPKD in the GCC/MENA regions

Experts note that the populations across GCC countries are diverse, with varying cultural customs. Based on previous studies from Tunisia, Oman, Kuwait and observations at regional centres, it is estimated that ADPKD affects 2–7% of dialysis patients in the GCC/MENA region. However, there's a lack of comprehensive clinical and statistical data on ADPKD prevalence due to the absence of robust population registries. Consequently, establishing national and GCC-wide registries is urgently needed to better understand the disease's prevalence and epidemiology in this region. While some small retrospective and genetic studies on ADPKD have been conducted in Middle Eastern populations, the Mayo imaging classification remains unvalidated in large, prospective cohorts from this region.

Awareness and training to enhance ADPKD diagnosis

All the experts indicated that radiologic imaging modalities provide essential information and guidelines for the diagnosis and management of ADPKD. They further disclosed that, despite the availability of both conventional and advanced techniques, there exist discrepancies in the diagnosis and management of ADPKD owing to false-positive results and misclassification, thereby highlighting the necessity for standardized imaging protocols (ADPKD protocol). Furthermore, according to experts, thorough reporting, enhanced awareness and targeted training for radiologists and technicians through workshops and seminars are imperative to reduce variations in image acquisition, processing and measurement and to prevent misclassification of ADPKD. Early referral to a nephrologist remains vital in ADPKD care, particularly for assessing renal parameters, such as TKV and genetic information, which are crucial for risk evaluation and informed decision-making regarding the initiation of disease-modifying therapies, such as Tolvaptan. Furthermore, the experts highlighted that, in addition to pharmacological treatments, supportive strategies from nephrologists, such as managing blood pressure, controlling pain and providing nutritional and genetic counselling, are essential for slowing the progression of the disease.

Use of tolvaptan in the ADPKD population across GCC/MENA regions

Experts emphasized that Tolvaptan has been approved in numerous countries for the management of ADPKD; however, its use remains limited among ADPKD patients in the Gulf Cooperation Council (GCC) and the Middle East and North Africa (MENA) regions, despite the higher prevalence of the condition in these areas. Furthermore, the inaccessibility of Tolvaptan in these regions constitutes a significant obstacle to its broader application in the ADPKD patient population. Additionally, participants in major clinical trials, such as TEMPO 3:4 and REPRIS, predominantly originate from Europe and Asia, underscoring the paucity of data on the efficacy and safety of Tolvaptan among ADPKD patients in GCC and MENA. Given the substantial influence of genetic and ethnic factors on disease progression and treatment response in

ADPKD, acquiring data regarding Tolvaptan's use within the GCC and MENA populations is of paramount importance.

Eligibility criteria for using tolvaptan in the ADPKD population

- Based on recent KDIGO guidelines and available clinical data on ADPKD in the GCC/MENA population, experts have outlined specific eligibility criteria for Tolvaptan use in this group, which include:
- **Age:** Tolvaptan should be prescribed for adults aged 18 to 55 years. In special cases, it can also be prescribed for adults aged 56 to 65 if a rapid decline in kidney function is observed.
- **eGFR decline:** Prescribe Tolvaptan if there is a sustained decline in kidney function greater than 3 mL/min/year over at least four years OR 5 mL/min over one year.
- **Kidney length:** Patients under 46 years old with kidney length exceeding 16.5 cm are likely to have Mayo Class 1C or higher and are considered high risk for ADPKD progression and may be treated with Tolvaptan.
- **TKV:** Patients younger than 50 with TKV above 750 mL are classified as high risk and candidates for Tolvaptan.
- **Mayo imaging classification:** Patients categorized as high risk (categories 1C, 1D, or 1E) according to Mayo Classification are suitable candidates.
- **Pro-PKD score:** The PRO-PKD score combines clinical and genetic data to predict the risk of ESKD and can aid in patient risk stratification and insurance approval for Tolvaptan. A score of 7 or higher indicates a high risk of kidney failure before age 60.

Initiation, titration and discontinuation of tolvaptan in the ADPKD population

For the GCC/MENA population, experts typically recommended initiating a dosing regimen of Tolvaptan to be taken 45 mg prior to the morning meal and 15 mg 8 hours later with or without food, in accordance with KDIGO guidelines. However, it was noted that some medical centers in the GCC/MENA region employ alternative practices, starting with lower doses (15/15 mg or 30/15 mg) to better address patient tolerability concerns and insurance coverage limitations. Certain clinicians adjust the Tolvaptan dosage based on Urine Osmolality (Uosm) to optimize therapeutic efficacy while managing severe aquaretic side effects. To guide titration, some practitioners employ first-void morning Uosm or an average 24-hour Uosm target of <250 mOsm/kg, though this approach is not universally adopted due to a lack of standardized evidence, variable interpretation and dose ceiling effects. Patients receiving Tolvaptan often experience polyuria during titration; however, most adapt over time. Additionally, pre-counseling patients regarding adverse effects such as polyuria can be beneficial in alleviating concerns.

Although clinical trials such as REPRISE have demonstrated the effectiveness of Tolvaptan in patients with eGFR as low as 25 mL/min/1.73 m², there is no data supporting Tolvaptan initiation below this threshold. Given the unfavorable risk-benefit profile of initiating Tolvaptan at advanced stages of ADPKD, experts recommend against initiating Tolvaptan when the eGFR is below 30 mL/min/1.73 m². For patients already on Tolvaptan, many clinicians continue the medication even if their eGFR falls below 30, until the patient reaches ESKD and requires dialysis or a kidney transplant.

Monitoring ADPKD patients taking tolvaptan to ensure safety

As per the experts, regular and scheduled LFT monitoring is mandatory in ADPKD patients for early detection to prevent the potential risk of severe liver damage. LFTs are checked frequently at 2 and 4 weeks after treatment initiation for initial monitoring. Then, for the first 18 months of treatment, LFTs are monitored monthly to assess the liver enzyme elevations. If found stable, LFT frequency is reduced to every three months. Based on LFT results, if ALT is greater than twice (>2X) the Upper Limit of Normal (ULN), Tolvaptan should be suspended and if ALT is greater than thrice the ULN (>3X ULN),

Tolvaptan should be stopped, while it should be permanently discontinued if ALT is recurrent or greater than five times the ULN (>5X ULN). It is also strictly instructed to follow the sick-day rule and withhold Tolvaptan during acute illness, in patients at high risk of dehydration and in patients under NPO status. Tolvaptan is contraindicated during pregnancy to avoid risk to the fetus, active liver disease to avoid potential severe liver injury, uncontrolled hypernatremia to avoid serious neurological problems, significant uric acid abnormalities to avoid hyperuricemia and gout and during inability to maintain hydration.

Guidelines for using tolvaptan in special populations

Experts emphasized that using Tolvaptan in special populations, such as women of childbearing age and older adults with ADPKD, demands careful consideration and tailored management plans. These aim to balance the medication's benefits with age-related factors, potential risks and side effects.

- **Women of childbearing potential:** Since Tolvaptan can cause reproductive toxicity and pose risks to the fetus, it is essential for women of reproductive age to use effective contraception before and during treatment. Among various contraceptive methods, progesterone-only pills are recommended for ADPKD patients taking Tolvaptan to minimize the cardiovascular risks associated with estrogen. Additionally, due to the potential dangers of fetal harm and liver injury related to Tolvaptan, thorough counselling is crucial. As written consent may be debated, the counselling process and verbal consent should be properly documented in the patient's medical records.
- **Older patients:** Typically, experts do not recommend starting Tolvaptan in patients over 55 due to its limited effectiveness in this age group. However, it can be considered for patients up to 65 years old if there is documented evidence of a rapid decline in kidney function. Additionally, Tolvaptan offers limited benefits for patients over 65 who still have relatively preserved renal function.

Guidance for ADPKD patients on tolvaptan during ramadan fasting

Some experts strictly advise ADPKD patients on Tolvaptan not to undergo fasting for their safety. However, others support an individualized approach allowing fasting by ADPKD patients on Tolvaptan with close monitoring. However, prioritising the patient's safety, all the experts unanimously recommend and advise not using Tolvaptan during fasting periods, considering the high risk of dehydration. However, if patients wish to fast, they should be thoroughly counselled, closely monitored, or advised to temporarily hold therapy.

Adjunct therapies and comorbidities in the management of ADPKD

In accordance with the prevailing clinical guidelines established by KDIGO, experts have proposed the following adjunct therapies for patients with ADPKD in the GCC/MENA region, including:

- **Managing blood pressure:** A target below 130/80 mmHg is suitable for ADPKD patients, with an ideal goal of 120/80 mmHg if tolerated [26].
- **RAS inhibitors:** RAS inhibitors, such as ACEi (Angiotensin-converting enzyme inhibitors) or ARBs (Angiotensin II receptor blockers), are regarded as the first-line therapy for proteinuria and hypertension in ADPKD patients due to their beneficial effects on renal hemodynamics and proteinuria [27].
- **SGLT2 inhibitors:** According to KDIGO 2025 ADPKD guidelines, SGLT2 inhibitors are not recommended as disease-modifying therapy in ADPKD due to risks of volume depletion, urinary tract infections and potential vasopressin stimulation. Their use may be considered in patients with comorbid heart failure or diabetes [22]. Nonetheless, a dedicated ADPKD trial (EMPA-PKD) is currently underway to evaluate the safety and efficacy of SGLT2 inhibitors in ADPKD [28].

- **GLP-1 RAs:** GLP-1 RAs are often considered for ADPKD patients because of their weight loss and anti-inflammatory properties, which can slow disease progression. They provide renal and cardiovascular benefits, especially for patients with type 2 diabetes and obesity [29]. However, in the GCC region, access to GLP-1 RAs via public healthcare or insurance is limited.
- **Finerenones:** These are non-steroidal mineralocorticoid receptor antagonists that offer cardiorenal benefits and are employed for the treatment of diabetic CKD with albuminuria [30]. Although animal studies have shown promising benefits of finerenones in ADPKD, there is no clinical study demonstrating the benefit of finerenones in slowing cyst growth or kidney function decline in ADPKD [31]. The non-steroidal Mineralocorticoid Receptor Antagonists (nsMRAs) are currently not recommended as disease-modifying therapy in ADPKD.
- **LDL cholesterol target:** According to the guidelines, ADPKD patients at high risk of cardiovascular disease should aim for LDL cholesterol levels below 1.8 mmol/L [32].
- **Sick day rule:** Patient should be instructed to temporarily withhold tolvaptan if they are sick (e.g., vomiting, diarrhea, fever, poor intake, etc.). Additionally, patients should be advised to avoid exposure to hot environments during extremely hot, prolonged summers.

Overview of Experts Discussion

Overall, during this meeting, experts put forward the main consensus statements aimed at improving ADPKD management in the GCC/MENA region:

Creating regional and national ADPKD registries within the GCC/MENA regions

Experts emphasize the importance of regional and national registries that can provide more precise and complete data on the history and current prevalence of ADPKD within the GCC/MENA population. Furthermore, these registries serve as vital resources for research, policymaking, management and the development of patient-focused treatment strategies for ADPKD.

Implement standardized imaging protocols (ADPKD protocol) for diagnosis and monitoring

Considering the ambiguity present in current imaging protocols, experts emphasized the necessity for a standardized protocol (ADPKD protocol), encompassing MRI and non-contrast, ultra-low-dose CT modalities in addition to ultrasonography. Implementation of such standardized procedures would facilitate more consistent and precise diagnosis of ADPKD across various centres and regions within GCC/MENA. Moreover, standardized protocols are essential for dependable disease monitoring, predicting disease progression and evaluating treatment response.

Necessity for research on treatment interruptions during Ramadan and their impacts

Fasting during Ramadan poses significant challenges for ADPKD patients taking Tolvaptan. Since Tolvaptan has aquaretic effects and requires steady hydration, fasting can lead to dehydration and electrolyte imbalances, increasing health risks. Experts recommend avoiding Tolvaptan during Ramadan and highlight the need for ongoing research to better understand how fasting and the interruption of Tolvaptan affect disease progression, treatment effectiveness and long-term outcomes.

Expand access to genetic counseling and testing

Since ADPKD is an inherited condition, experts recommend genetic counseling and testing options like NGS, WGS and Preimplantation Genetic Testing (PGT) during IVF as essential for family planning to prevent passing the mutation to future generations. However, these services are often limited in the GCC/MENA region due to their high cost, limited access and inconsistent insurance coverage. Increasing awareness, providing training

and implementing better policies are necessary to make these services more accessible and affordable.

Conclusion

ADPKD presents a significant health concern worldwide and is highly prevalent in the GCC/MENA regions. Due to the lack of comprehensive data on ADPKD prevalence and management within these regions, there is an essential need to establish regional or national registries dedicated to ADPKD, alongside the development of standardized protocols for its diagnosis and treatment. Given the prevalence of ADPKD and the demonstrated efficacy of Tolvaptan in its management, the utilization of Tolvaptan should be contemplated in the GCC/MENA regions in accordance with the recommended guidelines for initiation, optimization, assessment and monitoring of therapy. In summary, effective management of ADPKD requires a strategic shift toward enhancing patients' quality of life and long-term outcomes by prioritizing comprehensive data collection, the advancement of diagnostic and monitoring tools, facilitating access to genetic testing and adopting a patient-centered approach.

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Conflict of Interest

No conflict of interest.

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