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Improving Awareness & Patient Outcomes

Autosomal Dominant Polycystic Kidney Disease:

The Role of Imaging in Diagnosis and Prognosis

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Improving Awareness & Patient Outcomes

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Presenters

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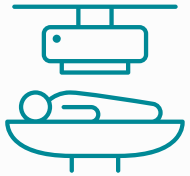
ADPKD Has a Spectrum of Clinical and Imaging Features That Have Direct Prognostic Implications

Understand the importance of TKV in disease prognosis in ADPKD



Explore different imaging modalities for measuring TKV, including new automated methods

Review the use of imaging to assess ADPKD complications

Discuss methods to facilitate successful communication between nephrologists and radiologists

ADPKD=autosomal dominant polycystic kidney disease. TKV=total kidney volume.

Suggested Guidance for Radiologists Reporting ADPKD Cases[1]

ADPKD—How to Report

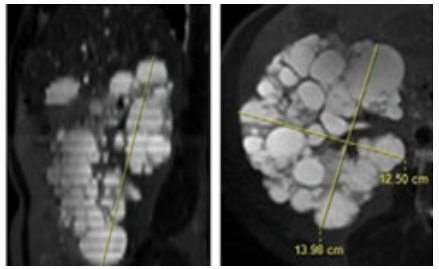
Step 1
Exclude the mimics.

Step 2
Confirm the diagnosis as per Unified Diagnostic Criteria.

Age (years)	Imaging findings
15-29	Total of ≥3 cysts
30-39	Total of ≥3 cysts
40-59	≥2 cysts in each kidney

Step 3
Classify as class 1 (typical) or class 2 (atypical).*
- Class 1: Typical, bilateral diffuse distribution
- Class 2: Unilateral, segmental, asymmetric, lopsided, bilateral with unilateral atrophy, bilateral with bilateral atrophy

Step 4a
Perform renal size and volume measurements.

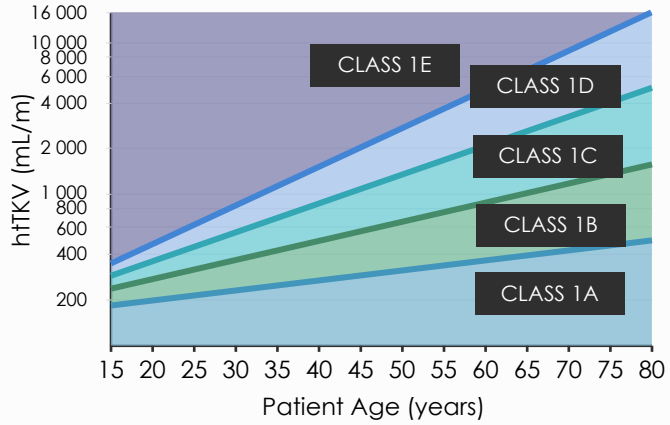


Ellipsoid Formula

$$\frac{\pi}{6} \bullet (TV \times AP \times CC) = TKV$$

TV: Maximal kidney **width** in the axial plane
AP: Maximal kidney **depth** in the axial plane
CC: Maximal kidney **length** in the coronal or sagittal plane

Step 4b
Calculate htTKV and assign Mayo classification.



$$htTKV = \frac{TKV}{height}$$

Step 5
Report any complications or extrarenal findings (eg, cysts in other organs).

Figure adapted from Odedra D, et al.

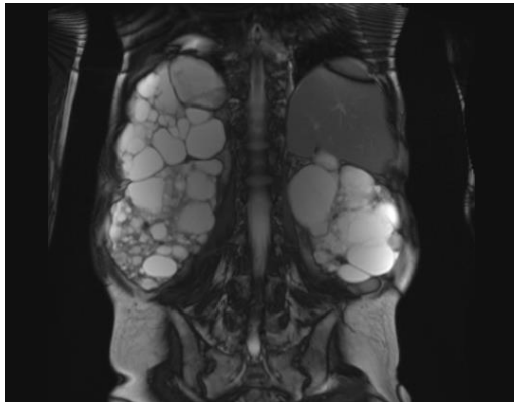
*Classifications are based on the MCIC.
AP=anterior-posterior. CC=craniocaudal. htTKV=height-adjusted total kidney volume. MCIC=Mayo Clinic Imaging Classification. TKV=total kidney volume. TV=transverse.
1. Odedra D, et al. *Radiographics*. 2023;43(1):e220126.

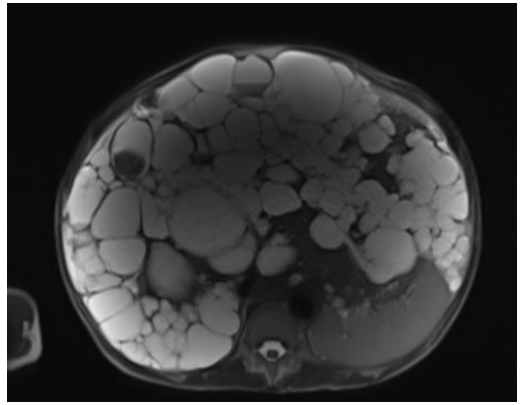
BACKGROUND AND DIAGNOSIS

ADPKD Is the Most Common Life-threatening Inherited Renal Disease[1]

ADPKD is a genetic disorder characterized by the **development and progressive enlargement of cysts in the kidneys** and other organs, eventually leading to ESKD[2]

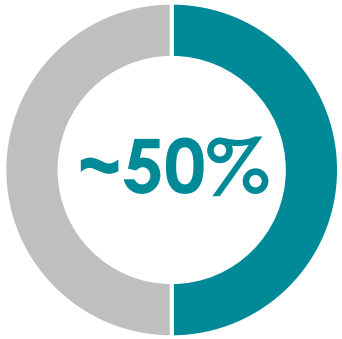
- ADPKD is caused by a *PKD1* or *PKD2* gene mutation inherited as an autosomal dominant trait





Images used with permission from Dr. Neera Dahl.

- The prevalence of ADPKD in the United States is about 140,000 individuals[3]
- ADPKD is the **fourth leading cause** of ESKD in the United States after diabetes, hypertension, and glomerulonephritis[4]
  - ADPKD accounts for **5% to 10% of ESKD cases[2]**



of ADPKD patients progress to ESKD by **age 60[2]**

ESKD=end-stage kidney disease. PKD1/2=polycystic kidney disease type 1/2.

1. Torres VE, et al. *Lancet*. 2007;369(9569):1287-1301. 2. Chebib FT, et al. *Am J Kidney Dis*. 2016;67(5):792-810. 3. Willey C, et al. *Kidney Dis*. 2019;5:107-117. 4. United States Renal Data System. 2022. Accessed June 1, 2023. https://www.usrds.org/annual-data-report/previous-adrs/

Imaging Modalities Play a Key Role in the Diagnosis and Initial Assessment of ADPKD[1]

US

- Detects cysts >1 cm in diameter[2]
- Most commonly used for diagnosis[3]

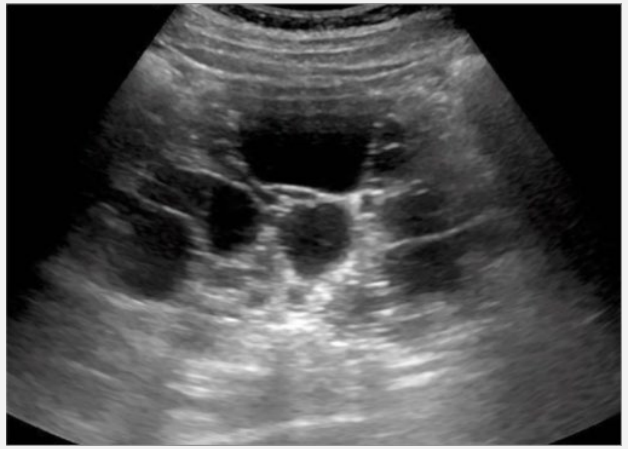


Figure from Cwojdzińska-Jankowska, et al.[4]

MRI

- Detects cysts ≥2 mm in diameter[2]
- Commonly used for follow-up[3]

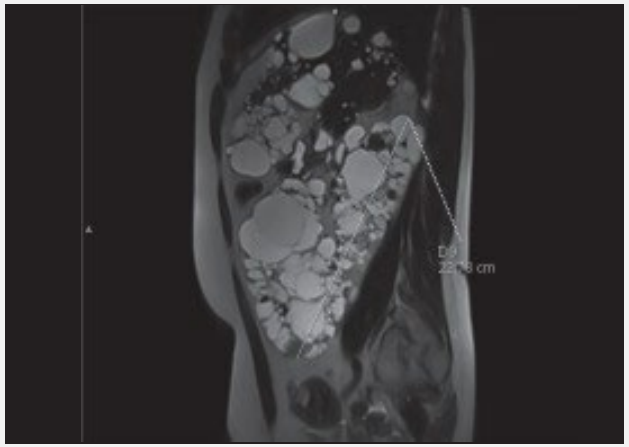


Figure from Banach-Ambroziak, et al.[5]

CT

- Detects cysts ≥2 mm in diameter[2]
- Commonly used for follow-up[3]

Figure from Onthoni, et al.[6]

Radiologists may play a vital role in recognizing the features of ADPKD mimics and proposing alternative diagnoses, when appropriate.[1]

CT=computed tomography. MRI=magnetic resonance imaging. US=ultrasound.

1. Odedra D, et al. *Radiographics.* 2023;43(1):e220126. 2. Magistroni R et al. *Am J Nephrol.* 2018;48(1):67-78. 3. Chebib FT, et al. *Am J Kidney Dis*. 2016;67(5):792-810. 4. Cwojdzińska-Jankowska I, et al. *J Ultrason.* 2013;13(54):344-349. 5. Banach-Ambroziak E, et al. *Pol J Radiol.* 2019;84:e289-e294. 6. Onthoni DD, et al. *Diagnostics (Basel)*. 2020;10(12):1113.

Cystic Kidneys Are Not Unique to ADPKD[1,2]

- Several other diseases can mimic ADPKD and present with renal cysts[1,2]
  - Confirming a diagnosis of ADPKD requires the exclusion of potential conditions which mimic ADPKD
- Congenital disease ADPKD mimics[1]
  - von Hippel-Lindau disease
  - Tuberous sclerosis
  - Medullary cystic disease
- Acquired ADPKD mimics[1]
  - Acquired cystic renal disease
  - Localized renal cystic disease

von Hippel-Lindau disease

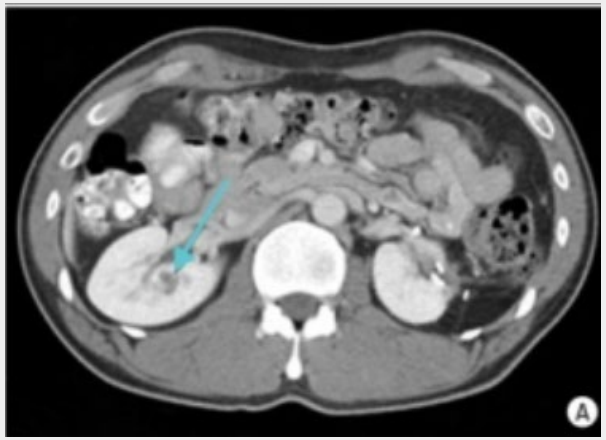


Figure from Kim HK, et al.[3]

Localized renal cystic disease

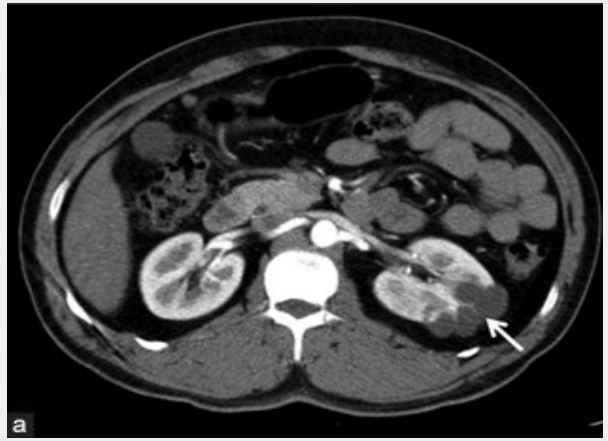


Figure from Narayanan R, et al.[4]

1. Odedra D, et al. *Radiographics*. 2023;43(1):e220126. 2. Gaur P, et al. *Br J Radiol*. 2019;92(1098):20190078. 3. Kim HK, et al. *Korean J Urol*. 2015;56(2):117-12.
4. Narayanan R, et al. *Indian J Urol.* 2015;31(2):146-147.

Screening for Renal Cell Carcinoma (RCC) Is an Important Part of ADPKD Diagnosis[1,2]

- RCC can mimic some of the clinical features of ADPKD, such as abdominal pain and kidney abnormalities, on imaging[3]
- Though RCC has been reported in patients with ADPKD, no causal link has been established[1,2]
- Ruling out RCC can ensure an accurate diagnosis and ultimately provide appropriate disease management for patients with ADPKD[1]
  - MRI can be extremely useful and advantageous in delineating benign from malignant lesions

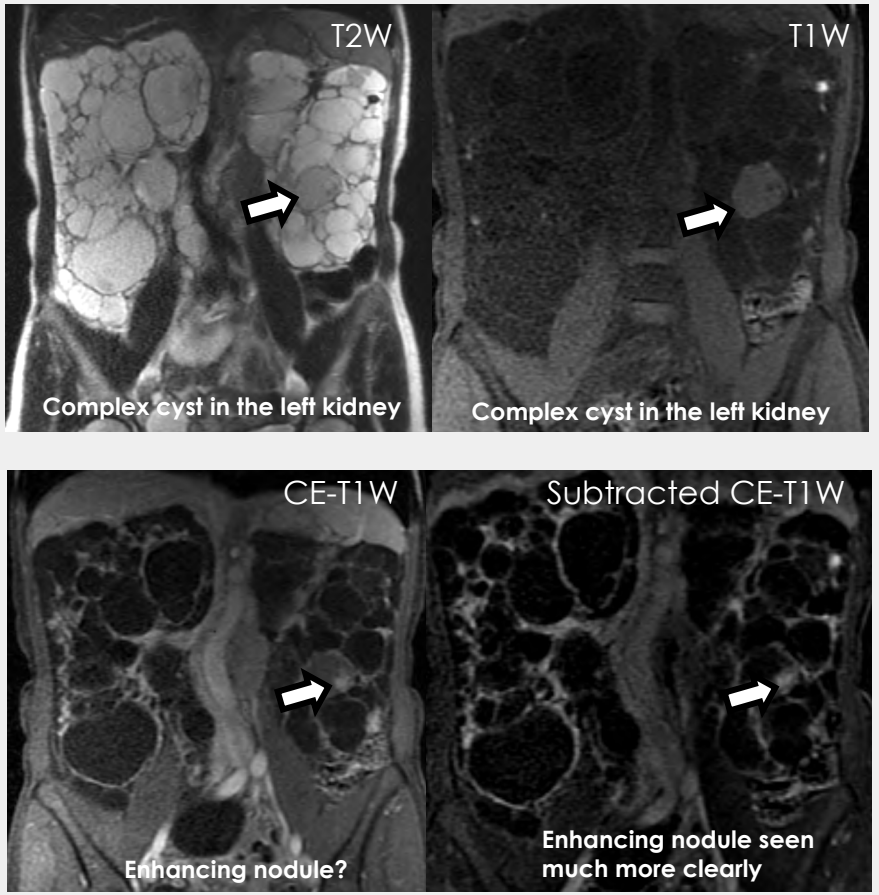


Figure from Odedra D, et al.[1]

CE=contrast enhanced. T1W=T1 weighted. T2W=T2 weighted.

1. Odedra D, et al. *Radiographics*. 2023;43(1):e220126. 2. Gaur P, et al. *Br J Radiol*. 2019;92(1098):20190078. 3. Hakozaki Y, et al. *CEN Case Rep*. 2021;10(2):199-207.

Imaging, Symptoms, and Family History Are Key to Diagnosing ADPKD

- **Diagnosis:** Family history + imaging findings[1,2]
  - **US is the most commonly used imaging method**
  - CT and MRI may also be useful when US results are indeterminate

Figure from Saedi, et al.[4]

Unified US Criteria for Diagnosis in Patients With Positive Family History (Pei Criteria)[1,3]

Age (year)	Number of cysts required for diagnosis
15-39	≥3 Unilateral or bilateral
40-59	≥2 each
≥60	≥4 each

1. Chebib FT, et al. *Am J Kidney Dis*. 2016;67(5):792-810. 2. Pei Y, et al. *J Am Soc Nephrol*. 2015;26(5):746-753. 3. Pei Y, et al. *J Am Soc Nephrol.* 2009;20(1):205-212. 4. Saedi D, et al. *Cases J*. 2009;2(1):66.

ADPKD Imaging Classification

Typical (Class I):

bilateral and diffuse cyst distribution in both kidneys[1]

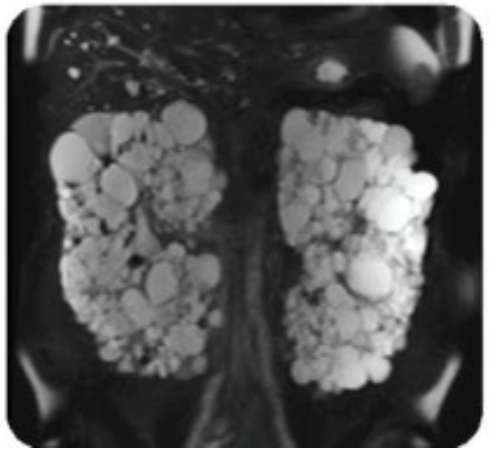
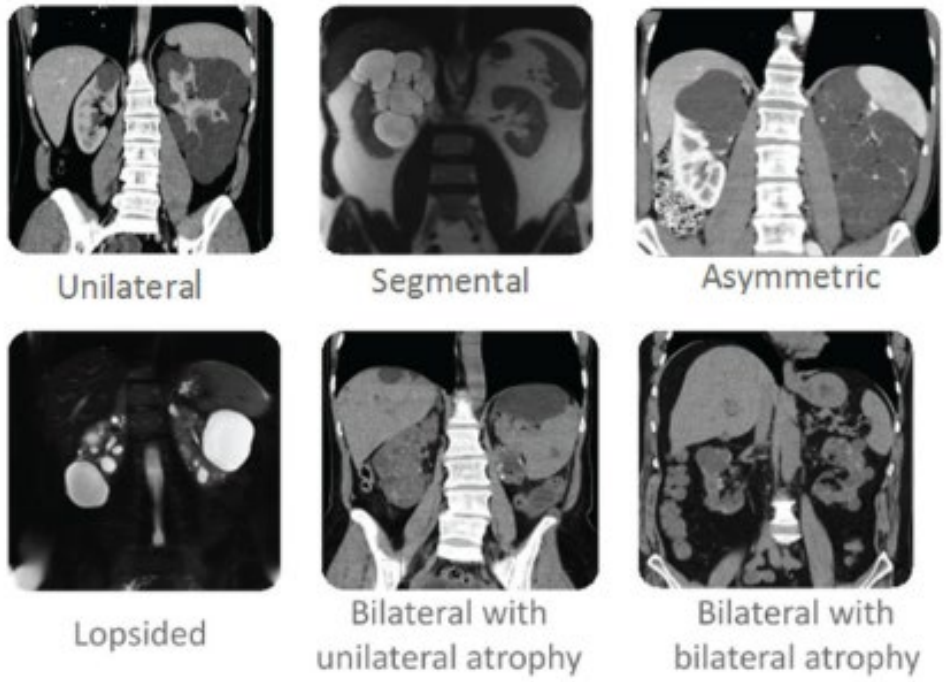


Figure from Soroka, et al.[3]

Atypical (Class 2):

do not fulfil the criteria for typical disease; TKV does not predict eGFR decline[1,2]



Figures from Soroka, et al.[3]

eGFR=estimated glomerular filtration rate.

1. Irazabal MV, et al. *J Am Soc Nephrol*. 2015;26(1):160-172. 2. Bae KT, et al. *J Am Soc Nephrol.* 2020;31(7):1640-1651. 3. Soroka S, et al. *Can J Kidney Health Dis*. 2018;5:2054358118801589.

PROGNOSIS AND RISK STRATIFICATION

Risk Factors That Could Be Associated With Rapid Disease Progression[1]

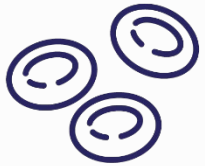
Rapid decline in eGFR[1]

TKV greater than expected for age[2]

Truncating *PKD1* mutation[3]

Family history of ESKD at or before age 58[1]

Hypertension before age 35[3]



Urologic events, such as hematuria, before age 35[3]

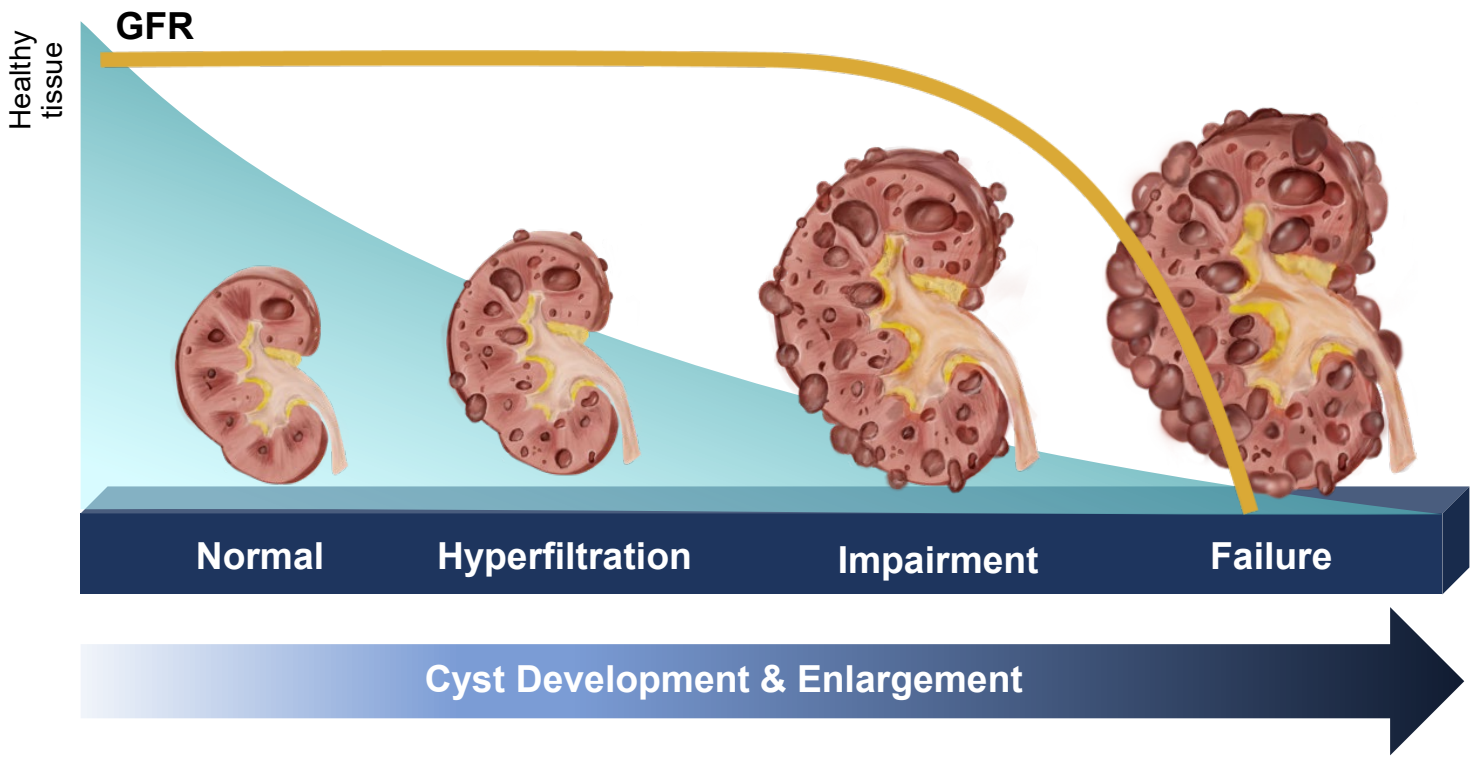
Overweight and obesity (BMI ≥25kg/m^2)[4]

Proteinuria and albuminuria[5]

BMI=body mass index.

1. Gansevoort RT, et al. *Nephrol Dial Transplant*. 2016;31(3):337-348. 2. Lanktree MB, et al. *Nat Rev Nephrol*. 2017;13(12):750-768. 3. Cornec-Le Gall E, et al. *J Am Soc Nephrol*. 2016;27(3):942-951. 4. Nowak KL, et al. *J Am Soc Nephrol*. 2018;29(2):571-578. 5. Schrier RW, et al. *J Am Soc Nephrol*. 2014;25(11):2399-2418.

Kidney Growth Precedes Decline in Kidney Function[1,2]



- Patients with ADPKD may remain asymptomatic for years while the disease progresses,[3] likely due to compensatory hyperfiltration[4]
- Irreversible tissue damage occurs by the time GFR declines[2]

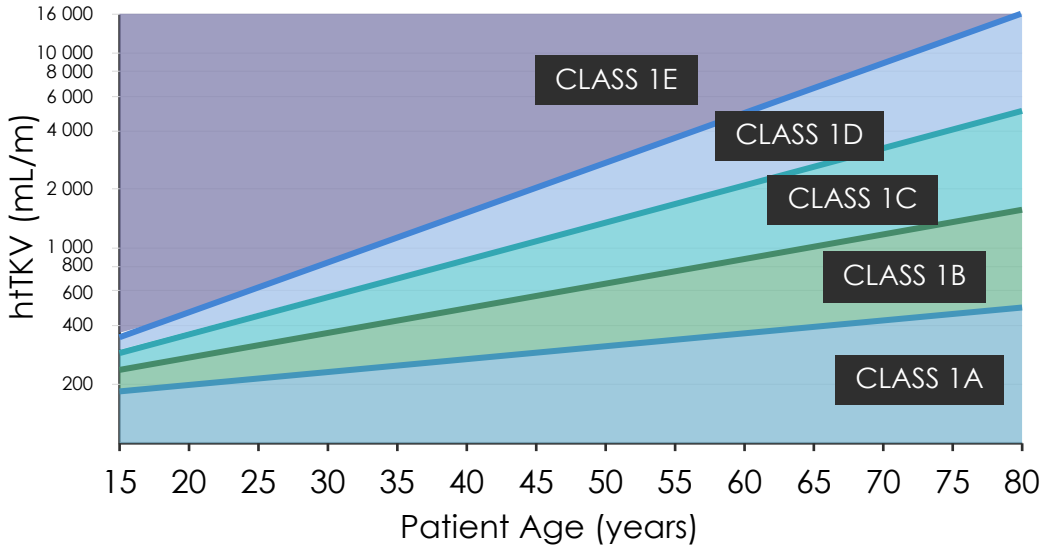
Monitoring eGFR alone may not capture ADPKD progression[1,2]

GFR=glomerular filtration rate.

1. Grantham JJ, et al. *Clin J Am Soc Nephrol*. 2006;1(1):148-157. 2. Grantham JJ, et al. *Nat Rev Nephrol*. 2011;7(10):556-566. 3. Lanktree MB, et al. *Nat Rev Nephrol*. 2017;13(12):750-768.
4. Meijer E, et al. Clin *J Am Soc Nephrol*. 2010;5(6):1091-1098.

TKV-based Classification of ADPKD[1]

Age and htTKV predict decline in eGFR over time in patients with typical* presentation of ADPKD



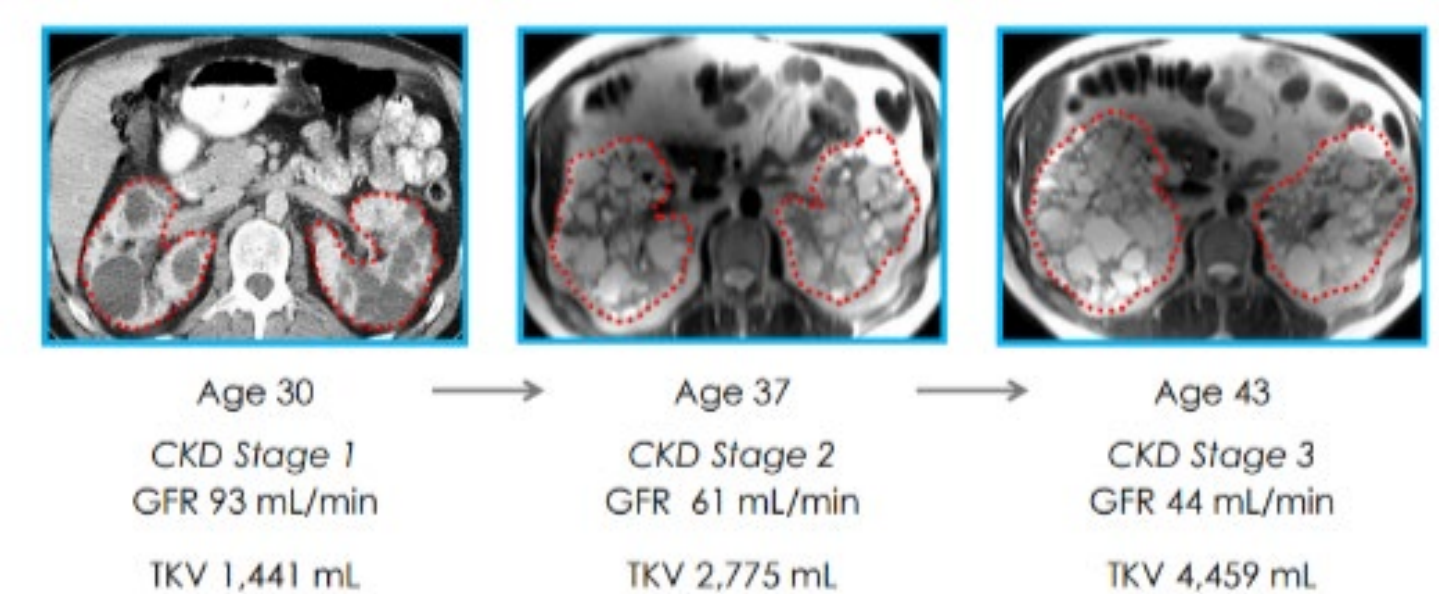
Class	Estimated kidney growth rate: yearly percentage increase	Risk for eGFR decline
1E	>6.0%	High risk
1D	4.5-6.0%	High risk
1C	3.0-4.5%	High risk
1B	1.5-3.0%	Intermediate risk
1A	<1.5%	Low risk

*Typical presentation patients with a bilateral and diffuse cyst distribution in both kidneys with mild to severe replacement of kidney tissue by cysts, with all cysts contributing similarly to TKV; atypical or class 2 ADPKD rate of eGFR decline cannot be calculated using this classification system.

1. Irazabal MV, et al. *J Am Soc Nephrol*. 2015;26(1):160-172.

TKV Is a Strong Predictor of Early-stage Disease Progression[1-3]

Over 13 years, TKV increased by 300%, with a 53% loss of kidney function[4]



In 2016, the FDA provided a recommendation for the use of TKV as a prognostic enrichment biomarker to select patients with ADPKD at high risk of progressive decline in renal function for inclusion in interventional clinical trials[5]

1. Chebib FT, et al. *Am J Kidney Dis.* 2016;67(5):792-810. 2. Grantham JJ, et al. *Nat Rev Nephrol.* 2016;12(11):667-677. 3. Bae KT, et al. *Nat Rev Nephrol.* 2010;6(2):96-106. 4. FDA Advisory Commitee. August 2013. Accessed June 6, 2023. http://web.archive.org/web/20170114002444/http:/www.fda.gov/downloads/AdvisoryCommittees/CommitteesMeetingMaterials/Drugs/CardiovascularandRenalDrugsAdvisoryCommittee/UCM364583.pdf 5. US Food and Drug Administration. September 2016. Accessed June 1, 2023. https://www.fda.gov/regulatory-information/search-fda-guidance-documents/qualification-biomarker-total-kidney-volume-studies-treatment-autosomal-dominant-polycystic-kidney.

METHODS FOR ESTIMATING TKV

Manual Planimetry

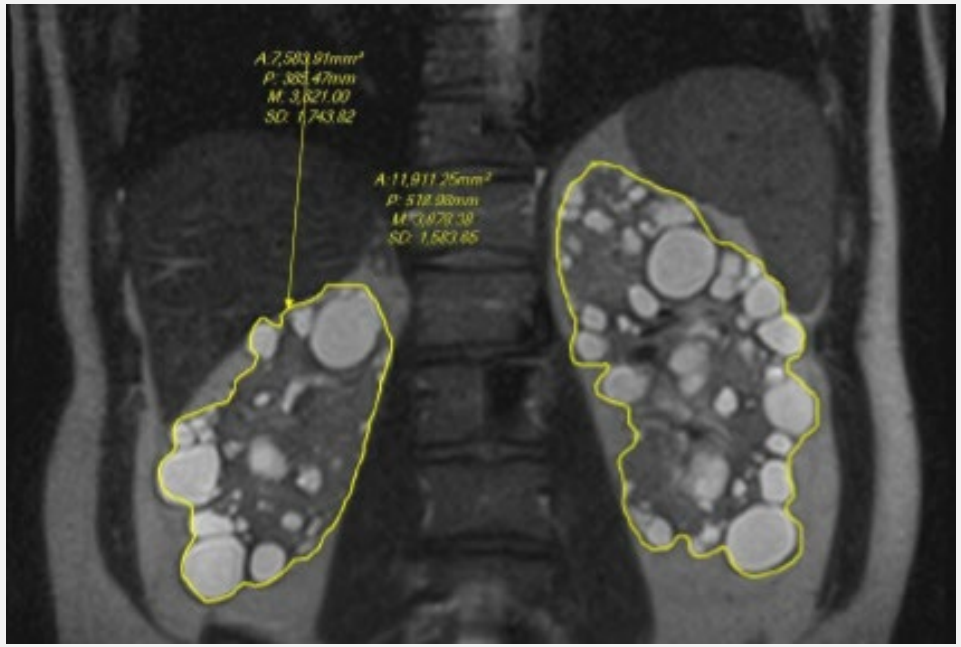


Image used with permission from Dr. Neera Dahl.

Planimetry with manual segmentation[1]:

- Traces kidney outline onto cross-sectional images
- Multiplies all traced areas by slice thickness
- Combines slice volumes

Accuracy[1]*:

- Highly accurate and reproducible (gold standard)

Time[2,3]: Variable

*Measurement accuracy according to the MCIC.

1. Odedra D, et al. *Radiographics.* 2023;43(1):e220126. 2. Magistroni R, et al. *Am J Nephrol*. 2018;48(1):67-78. 3. Demoulin N, et al. *Kidney Int Rep.* 2021;6(11):2821-2829.

Stereology

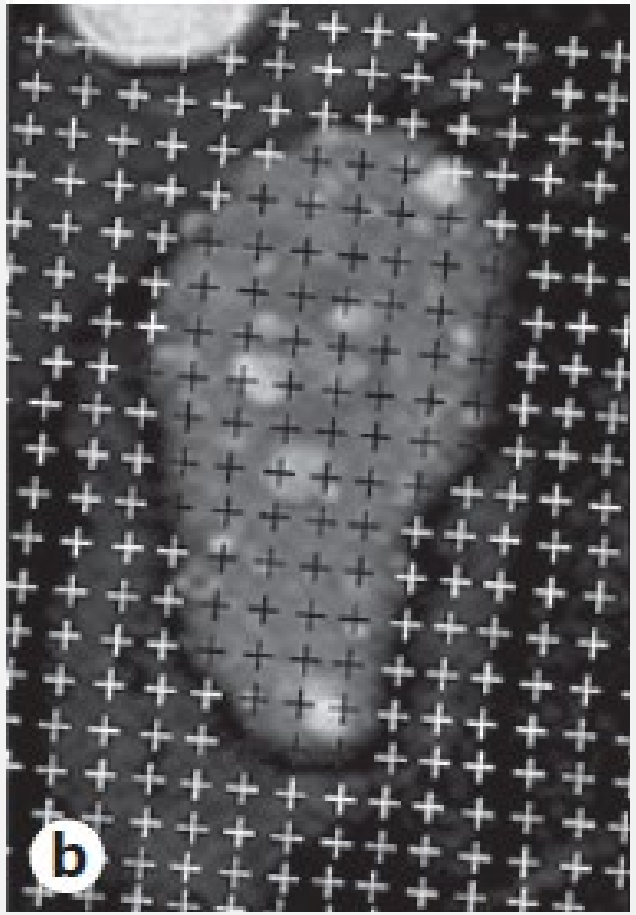


Figure from Magistroni, et al.[2]

Stereology[1]:

- Defines specific grid points corresponding to kidney regions
- Converts the number of grid points within the kidney to a pixel count and sums the pixels

Accuracy[1]: Comparable to manual planimetry

Time[2,3]: Time consuming

1. Odedra D, et al. *Radiographics*. 2023;43(1):e220126. 2. Magistroni R et al. *Am J Nephrol*. 2018;48(1):67-78. 3. Demoulin N, et al. *Kidney Int Rep*. 2021;6(11):2821-2829.

Ellipsoid Formula

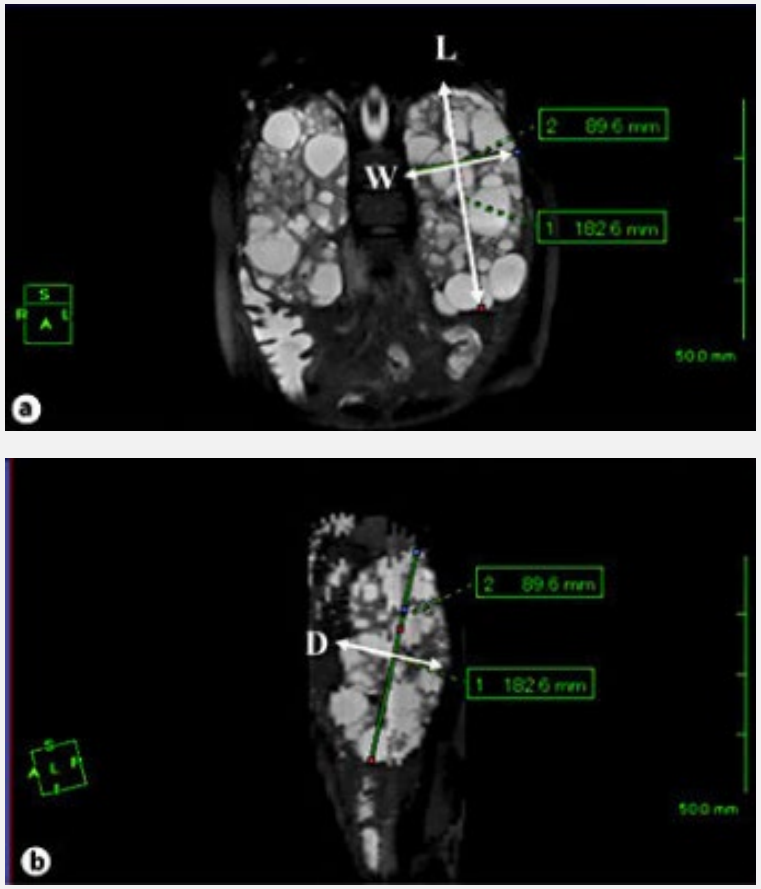


Figure from Higashihara, et al.[3]

Ellipsoid formula[1]:

- Takes three perpendicular measurements of the kidney to approximate TKV

$$\frac{\pi}{6} \cdot (CC \times TV \times AP\ x) = TKV$$

CC: Maximal kidney **length** in the coronal or sagittal plane

TV: Maximal kidney **width** in the axial plane

AP: Maximal kidney **depth** in the axial plane

Accuracy[2]*: Approx. 87%

Time[2]: Approx. 5 min

*Measurement accuracy according to the MCIC.

1. Odedra D, et al. *Radiographics*. 2023;43(1):e220126. 2. Magistroni R, et al. *Am J Nephrol*. 2018;48(1):67-78. 3. Higashihara E, et al. *Nephron*. 2015;129(4):253–262.

THE ROLE OF RADIOLOGY BEYOND TKV

ADPKD Is a Systemic Disease Characterized by Renal and Extrarenal Manifestations[1]

Renal Manifestations[1,2]

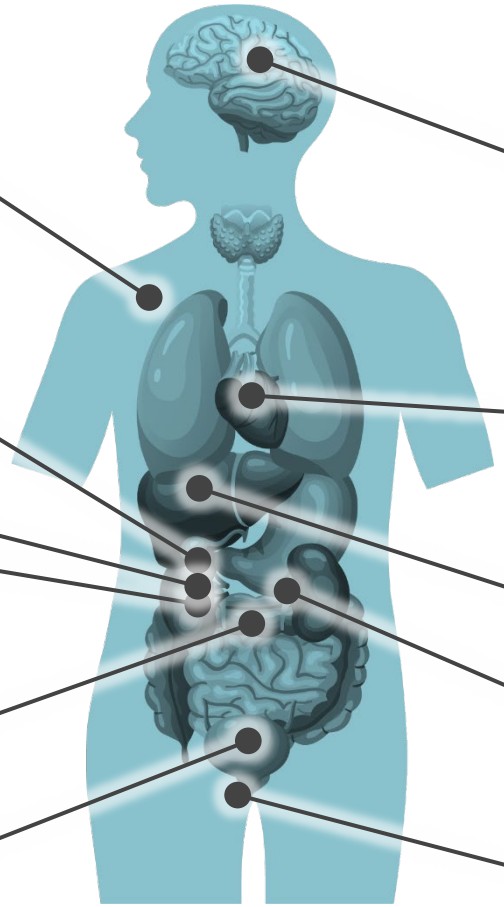
Hypertension

Renal cysts
Blood in urine

Palpable kidneys
Kidney stones

Abdominal/flank pain

Urinary tract infection



Extrarenal Manifestations[1,3]

Intracranial aneurysms
Arachnoid cysts

Valvular heart disease

Hepatic cysts

Pancreatic cysts

Seminal vesicle cysts

1. Chebib FT, et al. *Am J Kidney Dis.* 2016;67(5):792-810. 2. Halvorson CR, et al. *Int J Nephrol Renovasc Dis.* 2010;3:69-83. 3. Torres VE, et al. *Lancet*. 2007;369(9569):1287-1301.

Extrarenal Manifestations: Hepatic Cysts[1]

MRI Scan From an ADPKD Patient With Liver Cysts

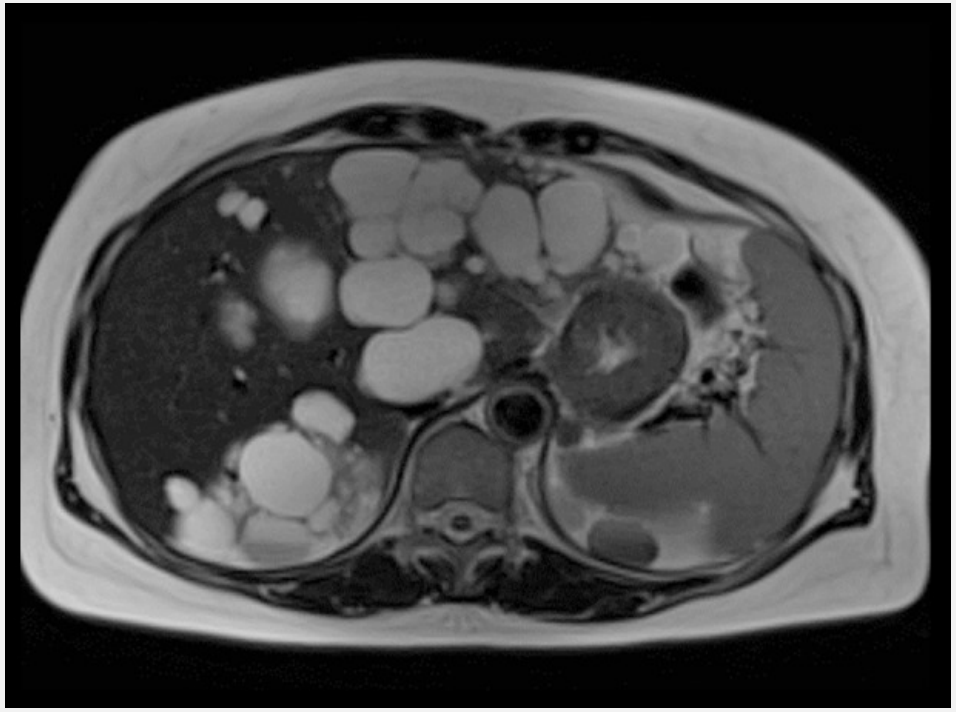


Figure from Gradzik, et al.

Screening for hepatic cysts is done at the time of diagnosis

- Hepatic cysts are detected in **85% of ADPKD patients >30 years old**
- The presence of hepatic cysts can provide an important clue for the diagnosis of ADPKD in patients with a negative family history for the disease

1. Gradzik M, et al. *Pol J Radiol*. 2016;43:441-453.

Extrarenal Manifestations: Intracranial Aneurysm (ICA)

MRA Scan From an ADPKD Patient With an ICA

Figure from Gradzik, et al.[1]

ICAs are at least twice as common in patients with ADPKD compared to the general population[2]

- Indications for screening **include the presence of CNS symptoms, a family history of ICA, or a high-risk occupation[2]**
- Screening MRA for aneurysms may be performed at age ≥20 years[3]
  - **If the screening result is negative, consider repeat screening every 5-10 years**
  - If an incidental aneurysm is detected, annual surveillance MRA is optimal

CNS=central nervous system. MRA=magnetic resonance angiography.

1. Gradzik M, et al. *Pol J Radiol*. 2016;43:441-453. 2. Chapman AB, et al. *Kidney Int*. 2015;88(1):17-27. 3. Odedra D, et al. *Radiographics*. 2023;43(1):e220126.

ADPKD With Complications

ADPKD With Hemorrhage

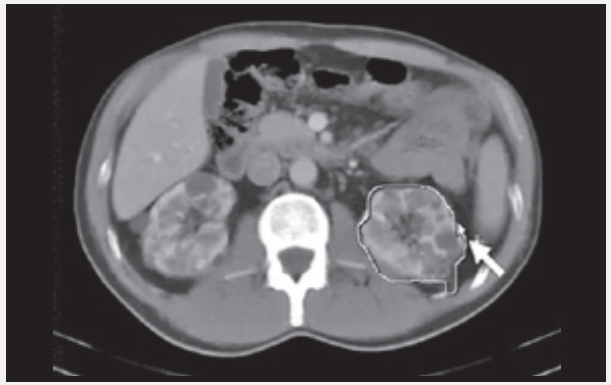


Figure from Magistroni, et al.[1]

ADPKD With Kidney Stones

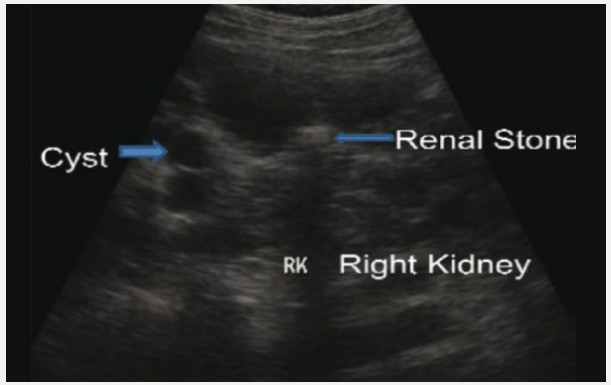


Figure from Baishya, et al.[2]

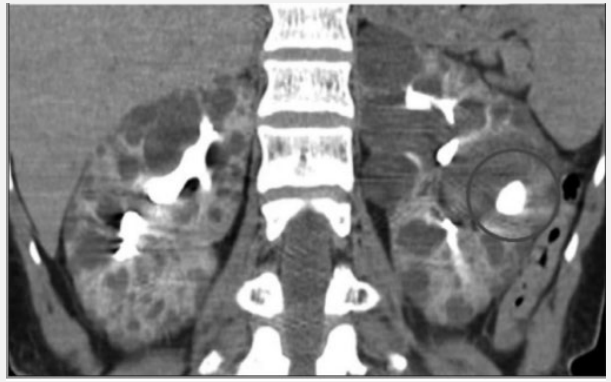


Figure from Baishya, et al.[2]

ADPKD With Infection

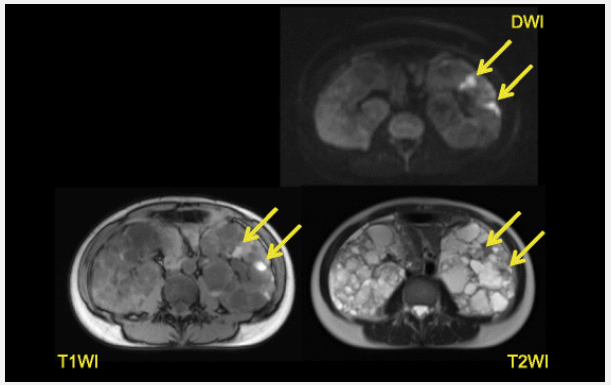


Figure from Suwabe, et al.[3]

1. Magistroni R et al. *Am J Nephrol*. 2018;48(1):67-78. 2. Baishya R, et al. *Urol Ann.* 2012;4(1):29-33. 3. Suwabe T, et al. *BMC Nephrol.* 2016;17(1):170.

MOVING FORWARD IN ADPKD IMAGING

Automated Segmentation Tools May Be Used to Overcome Obstacles and Accurately Measure TKV

Semiautomated and fully automated segmentation approaches using MRI or CT have been developed to address the challenges with traditional TKV measurement methods[1,2]

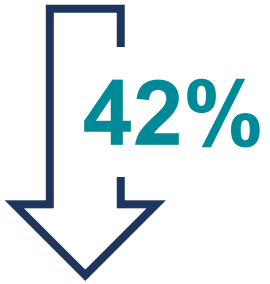
Advantages[2]:

- Fast
- Comparable accuracy and reproducibility to those of other methods

Disadvantages[2]:

- Still experimental and in early stages (not widely available)
- Requires additional software capabilities

Deep learning models may reduce the time required for radiologists to perform multiorgan segmentations in ADPKD and reduce measurement variability[3]



In one study, the use of a deep learning model reduced radiologist time required for segmentation from 33:04 to 19:17 minutes (*P*=0.001)

1. Magistroni R, et al. *Am J Nephrol*. 2018;48(1):67-78. 2. Odedra D, et al. *Radiographics*. 2023;43(1):e220126. 3. Sharbatdaran A, et al. *Tomography*. 2022;8(4):1804-1819.

Suggested Guidance for Radiologists Reporting ADPKD Cases[1]

ADPKD—How to Report

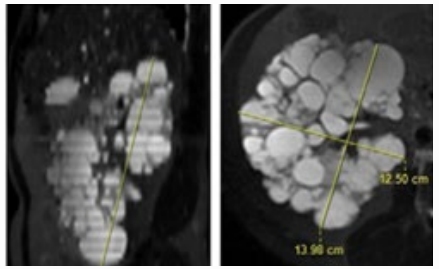
Step 1
Exclude the mimics.

Step 2
Confirm the diagnosis as per Unified Diagnostic Criteria.

Age (years)	Imaging findings
15-29	Total of ≥3 cysts
30-39	Total of ≥3 cysts
40-59	≥2 cysts in each kidney

Step 3
Classify as class 1 (typical) or class 2 (atypical).*
- Class 1: Typical, bilateral diffuse distribution
- Class 2: Unilateral, segmental, asymmetric, lopsided, bilateral with unilateral atrophy, bilateral with bilateral atrophy

Step 4a
Perform renal size and volume measurements.

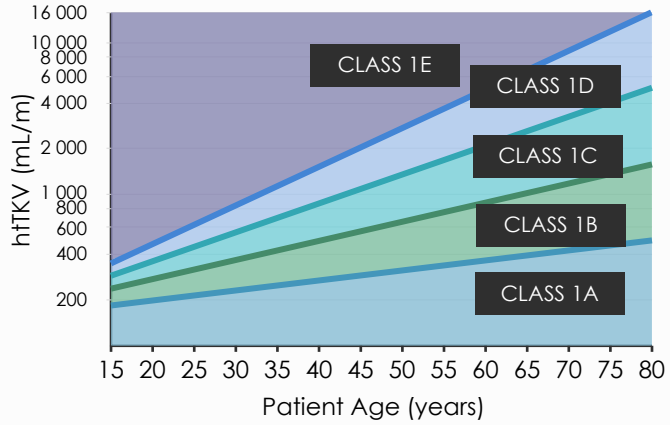


Ellipsoid Formula

$$\frac{\pi}{6} \bullet (TV \times AP \times CC) = TKV$$

TV: Maximal kidney **width** in the axial plane
AP: Maximal kidney **depth** in the axial plane
CC: Maximal kidney **length** in the coronal or sagittal plane

Step 4b
Calculate htTKV and assign Mayo classification.



$$htTKV = \frac{TKV}{height}$$

Step 5
Report any complications or extrarenal findings (eg, cysts in other organs).

Figure adapted from Odedra D, et al.

*Classifications are based on the MCIC.

1. Odedra D, et al. *Radiographics*. 2023;43(1):e220126.

Lack of Dedicated Billing Codes for TKV Measurement Poses a Challenge for Radiologists[1]

- Some radiologists have utilized existing codes to bill for TKV measurement
  - Codes 76376 and 76377 apply to 3-D rendering interpretation and reporting of CT, MRI, US, or other tomographic modality with imaging postprocessing[2]

Type	CPT-4 Code	Procedure
Abdominal MRI	74181	MRI abdomen w/o contrast
	74182	MRI abdomen w/contrast
	74183	MRI abdomen w/o and w/contrast
	74185	MRI abdomen
Abdominal CT	74150	CT abdomen w/o contrast
	74160	CT abdomen w/contrast
	74170	CT abdomen w/o and w/contrast
	74174	CT angio abdomen and pelvis contrast w/ and w/o contrast
	74175	CT angio abdomen with contrast/noncontrast
	74176	CT abdomen and pelvis w/o contrast
	74177	CT abdomen and pelvis w/contrast
	74178	CT abdomen and pelvis w/o contrast one or both body regions
Abdominal US	76700	US abdomen complete
	76705	US abdomen
3D rendering with interpretation	76376	3D rendering w/o independent workstation
	76377	3D rendering w/independent workstation

Angio=angiography. CPT-4=current procedural terminology, fourth edition. w/=with. w/o=without.

1. Sanon Aigbogun M, et al. *Int J Nephrol Renovasc Dis*. 2021;14:133-142. 2. Centers for Medicare & Medicaid Services. Billing and coding: 3D interpretation and reporting of imaging studies. CMS.gov. October 3, 2018. Accessed May 22, 2023. https://www.cms.gov/medicare-coverage-database/view/article.aspx?articleId=56920&ver=5

A Collaborative Partnership Between Radiology and Nephrology Is Key[1]

- A strong relationship between the radiologist and the nephrologist is crucial to obtaining the necessary information to aid in providing the best care for patients
- The radiologist has a central role in:
  - Establishing a diagnosis
  - Excluding mimics
  - Identifying complications
  - Assessing severity
  - Predicting future renal failure
- Communication is key!

1. Odedra D, et al. *Radiographics*. 2023;43(1):e220126.

SUMMARY

Radiologists play a key role in assisting in the diagnosis and prognosis of ADPKD[1]

Measurement of TKV is currently the best biomarker for staging and predicting disease progression[2]

Different methods of measuring TKV are utilized in clinical practice[1]

Report any complications or extrarenal findings evaluated on imaging[1]

Communication between radiologist and nephrologist is key[1]

1. Odedra D, et al. *Radiographics*. 2023;43(1):e220126. 2. US Food and Drug Administration. September 2016. Accessed June 1, 2023. https://www.fda.gov/regulatory-information/search-fda-guidance-documents/qualification-biomarker-total-kidney-volume-studies-treatment-autosomal-dominant-polycystic-kidney

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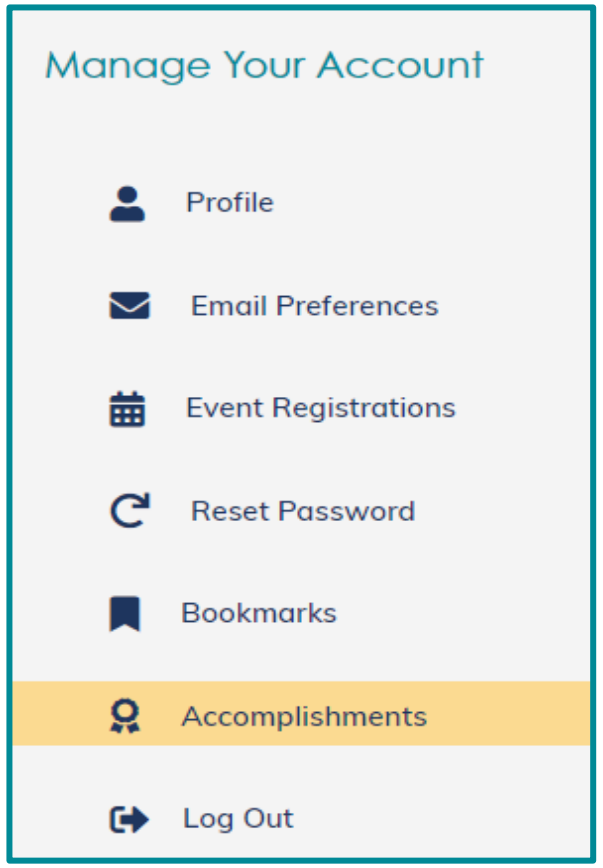

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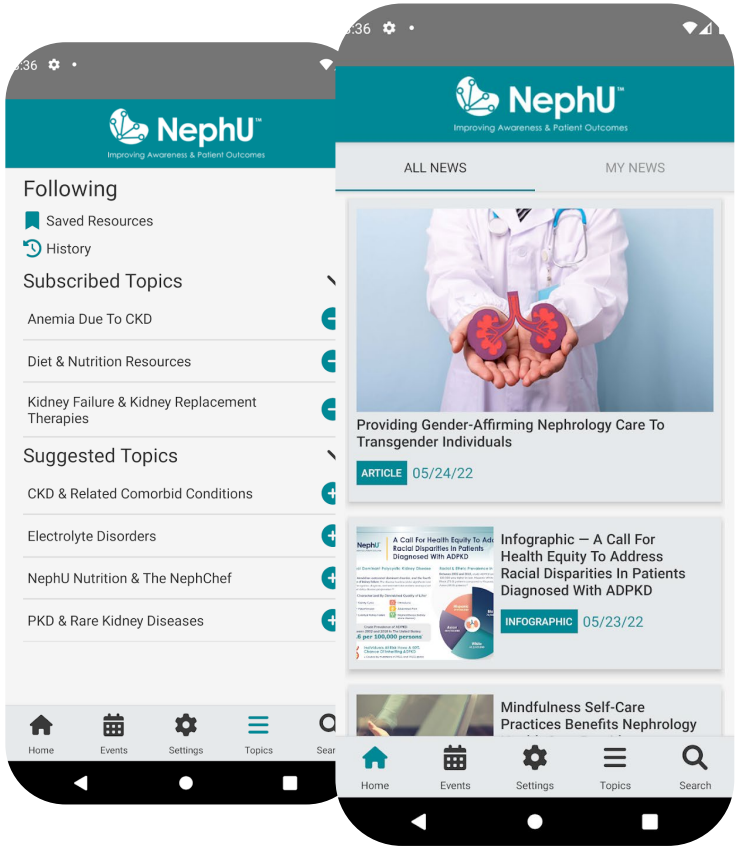

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