

BACKGROUND

- Polycystic kidney disease (ADPKD) & Autosomal Dominant Polycystic Liver Disease (ADPLD) are inherited disorders inducing cysts that progressively expand in kidney/ liver & multiply, causing mass symptoms & in ADPKD lead to renal failure.
- There is currently no effective treatment that can reduce both TKV & TLV in ADPKD & ADPLD patients.
- In 2017 we migrated from alcohol to sotradecol foam sclerotherapy (SFS) in our practice because of perceived improved efficacy in reducing total organ volume & relieving pressure symptoms and pain.

METHODS

- Data analyzed from 1/1/2017-12/31/2021 in those who completed at least one SFS procedure for cysts >5 cm diameter.
- Segmentation used to determine TKV/TLV & cyst volumes before & after SFS (in cases with coronal MRI/axial CT) using artificial intelligence software.
- Changes in TKV/TLV, kidney & liver function, QOL (LASA, PLD-Q, SF12) were evaluated.
- Impact on GFR decline, changes in TKV/TLV & adverse events (AEs) following SFS were assessed.
- TKV/TLV (absolute & % annual change wrt baseline, IQR [Q1,Q3], changes in PLD-Q scores were assessed pre/post, multivariable logistic regression examined GFR trajectories pre/post SFS.

RESULTS

Table 1: Demographics characteristics of the cohort at baseline

Age at procedure	Total (N=102)
N	102
Mean (SD)	58.1 (11.8)
Median	57.0
Q1, Q3	48.9, 67.6
Range	(30.5-82.6)
Gender	
Female	75 (73.5%)
Male	27 (26.5%)
Race	
White	96 (94.1%)
Black	2 (2.0%)
Asian	3 (2.9%)
Latin	1 (1.0%)
Diagnosis	
ADPKD	72 (70.6%)
ADPLD	8 (7.8%)
PKD spectrum	15 (14.7%)
Solitary cyst	7 (6.9%)
Genetic mutation	
PKDIT	15 (14.7%)
PKDINT	7 (6.9%)
PKDNT	10 (9.8%)
PKDNT	4 (3.9%)
Other	8 (7.8%)
Not known	58 (56.9%)

Table 2: Change in kidney volume and liver volume related measurements and result of the Signed Rank test

Change in TKV (mL)	Total (N=102)	p value
N	44	0.0001
Mean (SD)	-497.0 (739.8)	
Median	-348.0	
Q1, Q3	-554.5, -127.5	
Range	(-4397.0-735.0)	
% Change in TKV		<0.0001
N	44	
Mean (SD)	-25.8 (21.5)	
Median	-22.8	
Q1, Q3	-39.5, -8.7	
Range	(-69.6-16.8)	
Change in HT-TKV (mL/m)		0.0001
N	44	
Mean (SD)	-292.9 (436.2)	
Median	-212.4	
Q1, Q3	-314.4, -76.8	
Range	(-2586.5-431.3)	
Change in TLV (mL)		0.0001
N	53	
Mean (SD)	-271.6 (472.7)	
Median	-205.0	
Q1, Q3	-513.0, 39.0	
Range	(-1734.0-653.0)	
% Change in TLV		0.0003
N	53	
Mean (SD)	-11.0 (20.9)	
Median	-7.2	
Q1, Q3	-15.2, 1.6	
Range	(-109.8-12.7)	
Change in HT-TLV (mL/m)		0.0001
N	53	
Mean (SD)	-163.9 (281.3)	
Median	-124.0	
Q1, Q3	-311.1, 22.2	
Range	(-1001.7-385.0)	

RESULTS

Table 3: Average of the change in cyst volume and % change in cyst volume by patient, for each organ result of the Sign Rank test

	Total(N=100)	p value
Kidney cyst volume difference		<0.0001
N	44	
Mean (SD)	-281.3 (358.5)	
Median	-144.5	
Q1, Q3	-310.9, -85.0	
Range	(-1629.0--12.7)	
% Change in kidney cyst volume		<0.0001
N	44	
Mean (SD)	-83.1 (20.0)	
Median	-90.4	
Q1, Q3	-95.5, -77.8	
Range	(-100.0--9.0)	
Liver cyst volume difference		<0.0001
N	52	
Mean (SD)	-269.2 (396.2)	
Median	-107.6	
Q1, Q3	-261.3, -46.0	
Range	(-1937.0-14.9)	
% Change in liver cyst volume		<0.0001
N	52	
Mean (SD)	-64.8 (30.8)	
Median	-72.9	
Q1, Q3	-88.3, -39.1	
Range	(-100.0-49.7)	
Left kidney cyst volume difference		0.0006
N	27	
Mean (SD)	-265.7 (350.7)	
Median	-111.7	
Q1, Q3	-318.8, -61.0	
Range	(-1457.2--12.7)	
% Change in left kidney cyst volume		<0.0001
N	27	
Mean (SD)	-81.8 (16.6)	
Median	-84.4	
Q1, Q3	-94.7, -75.4	
Range	(-100.0--37.0)	
Right kidney cyst vol difference		0.0010
N	26	
Mean (SD)	-235.8 (323.9)	
Median	-121.7	
Q1, Q3	-276.1, -86.7	
Range	(-1629.0--18.9)	
% Change in right kidney cyst volume		<0.0001
N	26	
Mean (SD)	-85.2 (21.2)	
Median	-91.6	
Q1, Q3	-97.8, -83.3	
Range	(-100.0--9.0)	

Figure 1. Box plot representation of change in Ht-TKV (mL/m)

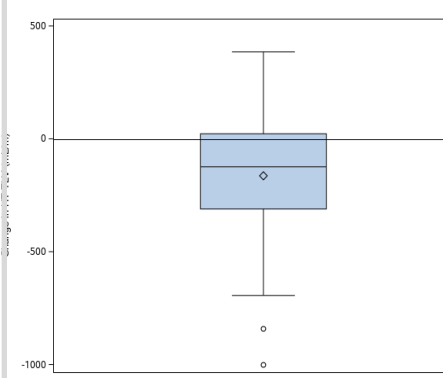


Figure 2. Box plot representation of change in Ht-TLV (mL/m)

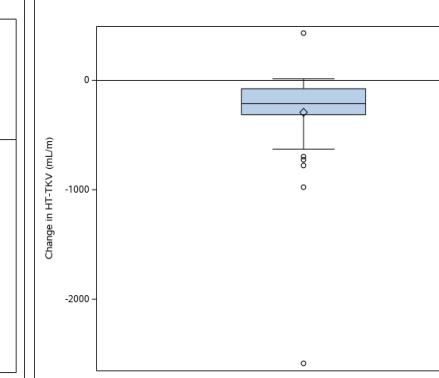


Figure 3. Box plot representation of percent difference of cyst volume by patient

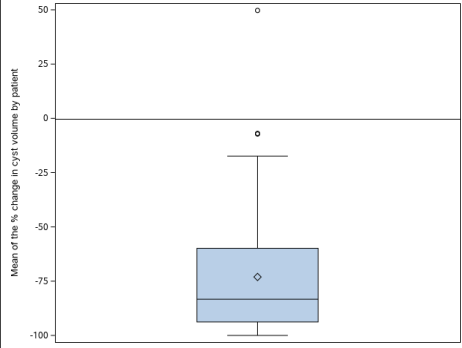


Figure 4. Box plot representation of mean difference of cyst volume by patient

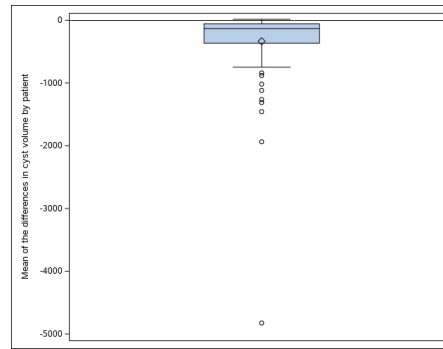
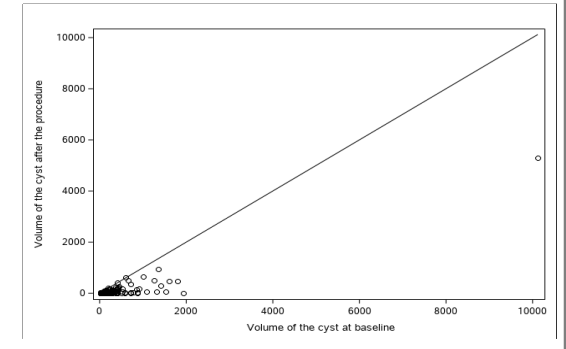


Figure 5. Scatterplot representation of individual cyst volumes before & after SFS demonstrates reduction in size in almost all cysts.



Adverse Events:

- Post procedural pain. n= 20 (20%)
- Five hospitalized (5%); cholangitis (n=1); hematuria associated with AV fistula R kidney (n=1) needing renal angiogram & embolization; hemoperitoneum (n=1) -resolved. Pain & nausea (n=1). Abdo pain (n=1).
- Other complications; (n=6; 6%). SOB (n=1; SOB) ER Visit; procedural pain (n=1); abortive procedure due to Sotradecol shortage Urine leak (n=1;1%) UTI (n=1; 1%) Contrast leak, (n=2; 2%).

CONCLUSIONS

- In those with pre & post SFS imaging, TKV (mean ± SD) decreased by 25.8 ± 21.5% & TLV by 11±20.9% with improvement in QOL-related reductions in mass effects. There was a 73±27.8% reduction in individual targeted cyst size; individual kidney cyst volumes decreased 83 ±20% and liver cyst volumes decreased 64.8 ± 30.8% While SFS did not augment effects on TKV and TLV in individuals on Tolvaptan and OctLAR, SFS was complementary with these medical therapies.
- There was no detectable benefit on eGFR decline in those who had SFS of kidney cysts in the ADPKD cases.
- We demonstrate clinical success with SFS as a relatively safe procedure (5% SAE rate) providing durable cyst volume reduction, improved pain and mass related symptoms and enhancing QOL.
- SFS can be performed as an outpatient day procedure with moderate sedation by Interventional Radiologists, replacing alcohol sclerotherapy & reduces the need for laparoscopic cyst fenestration for management of symptomatic liver & kidney cysts.

Pre- procedure

Post procedure

Cross- sectional imaging examples pre- and post-procedure. Cysts are circled.

