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Point Shear Wave Elastography (pSWE) for Evaluating Chronic Kidney Disease (CKD) in Adult Native Kidney with Histopathological Correlation

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ABSTRACT

Purpose: The purpose of this study was to examine the utility of point shear wave elastography (pSWE) in the diagnosis of chronic kidney disease (CKD) and the assessment of the degree of renal fibrosis.

Materials and methods: This study was performed at the Radiodiagnosis Department, Zagazig University. We examined 21 CKD patients who underwent renal biopsy and 21 healthy volunteers with conventional ultrasound and pSWE.Patients were classified according to the degree of renal fibrosis into four groups: non-fibrosis, mild, moderate, or severe fibrosis. All analyses were done using the Statistical Package for theSocial Sciences 20.0 software.

Results: The mean value of SWE (kPa) in patients (5.44±1.4) was more than (P=0.0001) that of healthy volunteers (2.5±1.00). The mean SWE values in the CKD stages were 3.65±0.9, 4.5±1.2, 5.8±0.5, 5.3±1.1, 6.6±0.9 kPa in stages 1,2,3,4, and 5 respectively. There was no significant difference between CKD stages except between stage 1 vs. 5 and stage 2 vs. 5. Only age showed a significant correlation with SWE in both CKD patients (r=0.453; P=0.039) and healthy volunteers (r=0.497; P=0.022). The histopathology revealed that 6 patients showed no fibrosis (4.0±1.1kPa), 11 patients showed mild fibrosis (6.0±1.0kPa), and 4 patients showed moderate fibrosis (5.9±1.2kPa), while no patients showed severe fibrosis. The cut-off value for predicting CKD was 4.05 kPa with 85.70% sensitivity and 90.5% specificity, while for predicting kidney fibrosis it was 4.45 kPa with a 93.30% sensitivity and 83.3% specificity.

Conclusion: Our findings imply that SWE is capable of discriminating between normal participants and patients with chronic kidney disease. Additionally, it is capable of detecting kidney fibrosis.

Keywords: chronic kidney disease, shear wave elastography, pathology, fibrosis.

1. INTRODUCTION

Chronic kidney disease (CKD) is a chief global public health problem. Its advanced stages are accompanied by high morbidity and mortality[1]. That is why it is vital to estimate its severity. CKD is defined as the presence of abnormalities of kidney structure or function for more than 3 months, with health implications [2]. It is diagnosed by the presence of one or more of the following: a prolonged reduction in glomerular filtration rate (GFR) to less than 60 ml/min/1.73 m2, the best indicator of renal function; or the presence of indicators for kidney injury such as albuminuria [3]. As CKD develops, it causes extensive tissue scarring, which leads to damage of kidney parenchyma. Renal fibrosis is nearly the ultimate common pathway for all CKD[4], and it is the main cause of kidney structural worsening and function loss[5].

Parenchymal damage is irreversible and can lead to further morbidity and mortality that is why early diagnosis and staging of fibrosis are important to detect prognosis and monitor disease progression. The existence and severity of fibrosis are a valuable predictor for disease evolution in chronic kidney diseases[6]. The gold standard current method to assess kidney fibrosis and renal scar burden is the histological assessment of needle biopsy samples[7]. However, renal biopsy has considerable limitations due to its invasive nature, high cost, inter-observer variability, and sampling error[8]. Thus, there is a great interest in developing non-invasive methods to assess renal interstitial fibrosis.

Ultrasound-based elastography is one of the most remarkable imaging techniques that evaluate the degree of tissue stiffness in living tissues, giving qualitative and quantitative data[9]. Acoustic Radiation Force Impulse (AFRI), one of the elastography based techniques, assesses the mechanical properties of tissues using short-duration, high-intensity pulses of acoustic radiation force to produce localized displacements in tissue and then tracks the tissue dynamic response [10]. Point shear wave

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elastography (pSWE) using ARFI can quantitate tissue elasticity. It is operator-independent using a conventional ultrasound machine with an ordinary ultrasound probe [11].

2. PATIENTS AND METHODS

This study was established after obtaining institutional review board approval and informed consent from patients before the study.

2.1. Patients

The study included two groups: the study group consisted of 21 CKD patients who underwent renal biopsy referred from the Nephrology Department of Zagazig University Hospitals from June 2019 to Mars 2020 and the control group consisted of 21 normal healthy volunteers who were enrolled at the site of the study.

Patients were included if they were over the age of 18 and had been diagnosed with chronic kidney disease; according to the National Kidney Foundation's (NKF) guidelines, CKD was defined as either kidney damage or an e-GFR of less than 60 ml/min/1.73 m2 for at least three months, regardless of the cause[12], e-GFR was calculated by serum creatinine based on the Modification of Diet in Renal Disease Study (MDRD) equation:$e\text{-}GFR\ (ml/min/1.73\ m^2) = 186 \times (Creatinine/88.4)^{-1.154} \times (Age)^{-0.203} \times (0.742\ if\ female) \times (1.212\ if\ African\ American)$[13]. Then patients were staged according to eGFR into stage 1 (eGFR ≥90), stage 2 (eGFR 60–89), stage 3 (eGFR 30–59), stage 4 (eGFR 15–29), and stage 5 (eGFR <15)[14].

Patients with a BMI greater than 35 kg/m2 or with any condition that prevents ultrasound vision of the kidney, such as pregnancy or noticeable ascites, patients with surgical kidney disorders such as hydro or pyonephrosis, or patients refusing to finish the study were excluded

2.2. *Methods*

a) Demographic and clinical data:

Demographic data including age, sex, and BMI, clinical data, and Laboratory resultsincluding serum creatinine and the urine albumin test were extracted from medical records or by interview.

b) Imaging acquisition:

Conventional ultrasound and point shear wave elastography examinations were performed by a single experienced ultrasonographer on Philips iU22 Ultrasound machine, (Philips Medical System, Bothell, WA) equipped with ELAST PQ software using C5-1 (1-5 MHz) convex probe.

c) Conventional US exam

The patient was placed in either the supine or lateral decubitus that achieved the best visualization of the kidney. A routine conventional ultrasound examination was done on both kidneys. On the coronal plane of the kidney, the renal length was measured as the maximum length between superior and inferior poles. Kidney depth was recorded as the distance of the kidney from the skin. Inability to visualize the kidneys in conventional ultrasound for any cause or presence of any renal surgical problems as stones, tumors, or hydronephrosis excluded the person from the study.

d) SWE Exam

Using the Elast PQ software, with the transducer set perpendicular to the renal capsule, regions of interest were placed in the cortex avoiding renal pyramids and blood vessels so that only cortical tissue was included, with specific consideration to keep the ROI parallel to the pyramids as possible. The YMs of the patient's kidney cortex was measured at end-inspiration with patients holding breath. Values were measured at mid kidney and both poles. In case of invalid measurement, the screen displayed 0 KPa, we repeated the measurement. At least ten effective measurements were recorded, and the mean value was calculated.

e) Histological evaluation

Renal biopsies were taken from the inferior pole of the kidney by experienced interventional radiologists. A histological assessment was done, then CKD patients were classified according to the degree of interstitial fibrosis declared in the result of the histological analysis into four groups non-fibrosis, mild fibrosis(fibrosis ≤25% of the sampled cortical area), moderate fibrosis (fibrosis 26-50% of the sampled cortical area) or severe fibrosis (fibrosis >50% of the sampled cortical area).

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f) Statistical analysis:

Data analysis was performed using the Statistical Package for the Social Sciences software (IBM Corporation, v. 20.0, Armonk, NY). Data were expressed as numbers and percentages for qualitative data and arithmetic mean ± Standard deviation (SD) for quantitative data. The differences in demographic features, US measurements, and Lab. values between healthy volunteers and CKD patients and among CKD patients were evaluated by one-way analysis of variance (ANOVA). When differences among them were found to be statistically significant ($P<0.05$), each group was compared with every other group using Tukey's post hoc test. Influencing factors such as eGFR, age, BMI, kidney length, and kidney depth were analyzed using Pearson's correlation coefficient (r). Diagnostic performance of ARFI in determining CKD and mild fibrosis was assessed using receiver operating characteristic (ROC) curves. The optimal cut-off values were chosen to maximize the sum of sensitivity and specificity. Statistical analysis was performed on the data collected and $P<0.05$ was recognized as statistically significant. The smaller the P value obtained the more significant is the result.

3. RESULTS

3.1. Patient Characteristics:

42 adults including 21 healthy volunteers (12 females and 9 males) and 21 CKD patients (13 females and 8 males) were assessed. The data of healthy volunteers and CKD patients are presented in **Table 1**. There was no significant difference in age, BMI, kidney length, or kidney depth between healthy volunteers and CKD patients, nor among the patients in stages of CKD **(Table 2).**

Table 1: Demographic features, US measurements, and Lab. values of CKD patients and control subjects:

Characteristic	Control N=21	CKD N=21	P[a]
Age (years)	36.1±12.2	34 ±14.8	0.619
BMI (kg/m$^{2)}$	24±3.1	25.6±2.7	0.072
Kidney length (cm)	10.5±1.00	10.4±1.3	0.776
Kidney depth (cm)	4±0.9	4.5±0.9	0.064
YM (kPa)	2.5±1.00*	5.44±1.4	0.0001
eGFR (ml min^{-1} / 1.73m^2)	> 90	44.1±37.7	
Fibrosis (%)		20.5±19.9	

Variables are expressed as mean ± SD,
[a]One way ANOVA is used to analyze the difference between the two groups,
* significant at $P<0.05$.

Table 2: Demographic features, Us measurements, and Lab. values among CKD stages:

Characteristic					P
	CKD1 N=3	CKD2 N=4	CKD3 N=4	CKD4 N=3	CKD5 N=7

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Age (years)	20.7±2.1	27.3±6.6	31.3±9.2	38.7±21.2	43.3±16.7	0.157
BMI (kg/m2)	23.3±1.0	26.4±3.4	25.1±3.1	26.2±2.9	26.3±2.5	0.525
Kidney length (cm)	11±0.4	10.5±1.0	11.3±0.5	10.1±1.5	9.7±1.7	0.352
Kidney depth (cm)	4.8±0.3	4.5±1.0	4.5±0.9	4.3±1.3	4.5±1.0	0.991
YM (kPa)	3.65±0.9[a]	4.5±1.2[ab]	5.8±0.5[bc]	5.3±1.1[abc]	6.6±0.9[c]	0.002
eGFR (ml min 1/ 1.73m²)	110±26.5[d]	71.5±10[c]	45.5±8.3[b]	23±6.2[ab]	8.3±2.8[a]	0.000
Fibrosis (%)	6.7±11.5	13.8±17.0	18.8±8.5	20.0±11.5	19.3±13.4	0.712

*[a]One way ANOVA is used to analyze the difference between the two groups,
Means with different superscripts (a, b, c, d) are significantly different at P<0.05.

3.2. Potential influencing factors:

Age in both CKD patients (r=0.453; P=0.039) and healthy volunteers (r=0.497; P=0.022) showed a significant moderate positive correlation with the SWE **(Figure 1)**. Yet, SWE showed no significant correlation with BMI, kidney length, or kidney depth in healthy volunteers nor CKD patients **(Table 3)**. SWE showed no significant difference between men and women in healthy volunteers (2.5±0.8 kPa vs. 2.5±1.1kPa, P=0.895) nor CKD patients (5.7±1.4 kPa vs. 5.3±1.3 kPa, P=0.468).

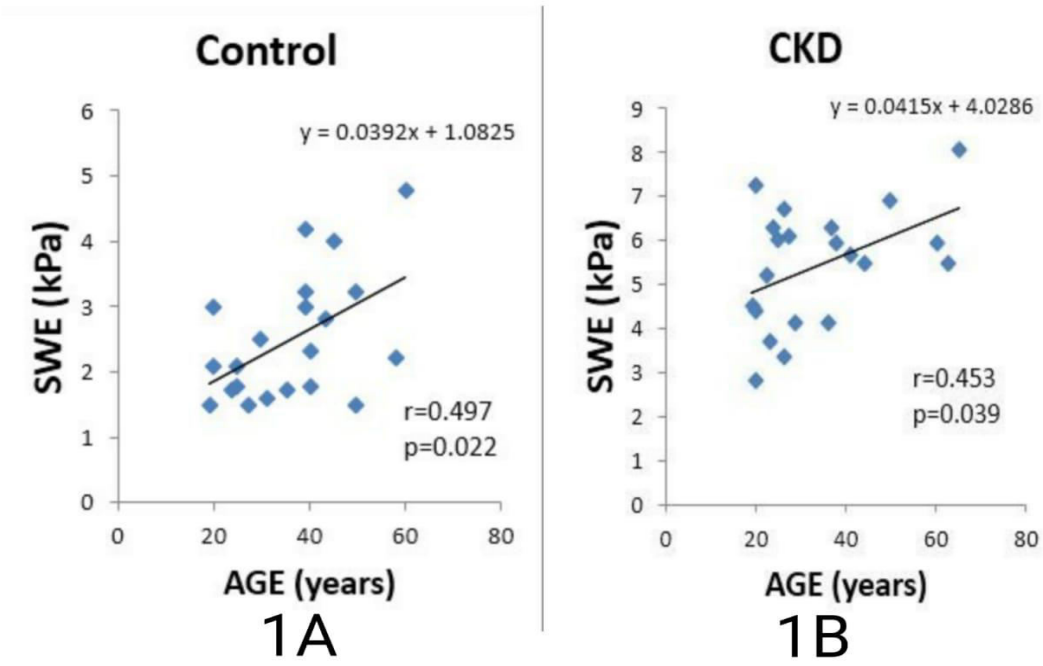

Figure 1: Correlation between SWE and **1A:** age in control subjects, **1B:** age in CKD patients.

Table 3: Correlation between SWE and different influencing factors in both control and CKD groups:

Variable	**CKD**	**Control**
	N=21	**N=21**

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	r	P	r	P
Age (years)	0.453	0.039	0.497	0.022
BMI (kg/m2)	0.168	0.467	-0.029	0.901
Kidney length (cm)	-0.118	0.610	0.136	0 .557
Kidney depth (cm)	-0.203	0.377	0.225	0.327
eGFR (ml min-1 / 1.73m²)	-0.637	0 .002		
Stage	0.749	0.000		

Correlation between SWE and variables are analyzed using Pearson's correlation coefficients.

3.3. SWE in healthy volunteers and CKD patients:

The mean value of SWE (kPa) in CKD patients (5.44±1.4) was more than twice (P=0.0001) that of the healthy volunteers (2.5±1.00). The mean SWE values in CKD stages were 3.65±0.9, 4.5±1.2, 5.8±0.5, 5.3±1.1, and 6.6±0.9 kPa in stages 1, 2, 3, 4, and 5 respectively **(Figure 2)**. Despite that the SWE values increased significantly (P=0.002) with the increase of the CKD stage reaching the highest value in patients at stage 5 (6.6±0.9 kPa), we found no significant difference between the different stages of CKD except between stage 1 vs. 5 and stage 2 vs. 5.

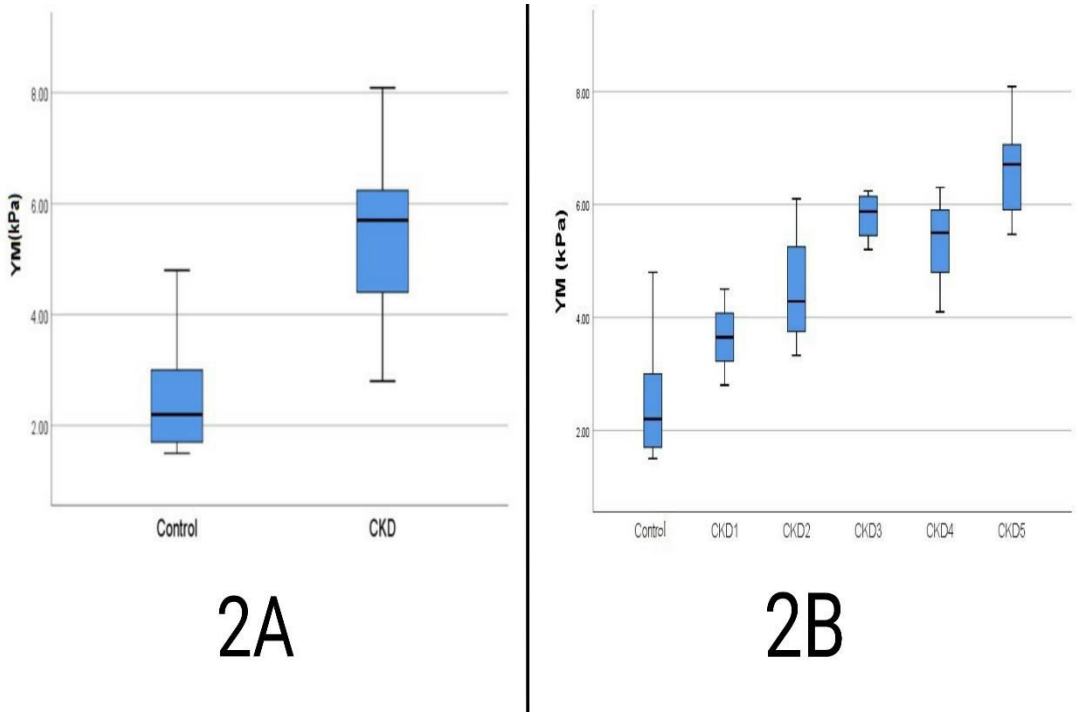

Figure 2: Mean YM values in **2A:** control subjects and CKD patients, and **2B:** control subjects and stages of CKD.

3.4. SWE according to the degree of renal fibrosis:

The result of histopathological analysis of renal biopsies taken from 21 CKD patients revealed that 6 patients showed no renal fibrosis, 11 patients showed a mild degree of renal fibrosis, and 4 patients showed a moderate degree of renal fibrosis, while no patients showed a severe degree of renal fibrosis.

YM values were significantly lower in CKD patients with no fibrosis (4.0±1.1) than in those with fibrosis (6.0±1.0) (P=0.008). However, YM values did not vary between the mild and moderate degrees of fibrosis **(Table 4, Figure 3)**. Age tends to be higher (P=0.052) in patients with fibrosis (37.3±16.0)

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than in those with no fibrosis (26.0±6.8). BMI showed no significant difference between healthy volunteers and CKD patients or between patients with mild and moderate degrees of fibrosis. Kidney length insignificantly decreased in patients with moderate fibrosis. EGFR was significantly higher (P=0.001) in patients with no fibrosis (56.8±38.0) than those with fibrosis (38.9±37.6), yet no significant difference between patients with mild and moderate fibrosis.

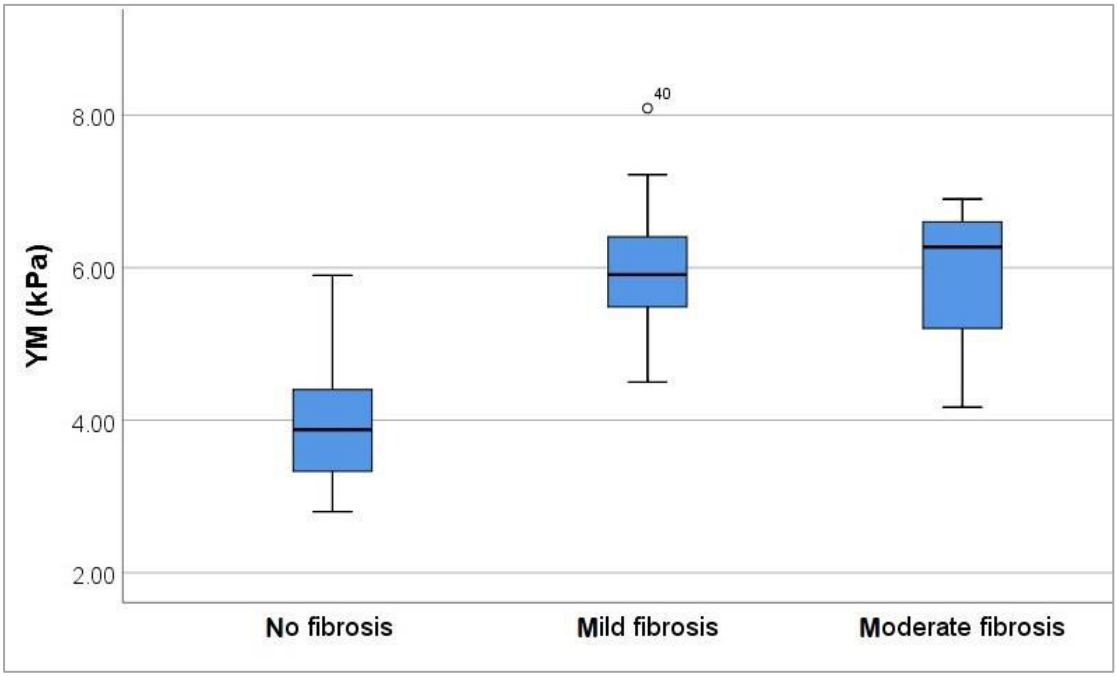

Figure 3: Mean values of SWE in CKD patients according to the degree of renal fibrosis.

Table 4: Demographic features, Us measurements, and Lab. values among CKD patients according to the degree of fibrosis:

Variable	No fibrosis N=6	Fibrosis N=15 Mean	Mild fibrosis N=11	Moderate fibrosis N=4
Fibrosis (%)	0.0±0.0	23.0±10.0	17.7±3.4	37.5±6.5
YM (kPa)	4.0±1.1[a]	6.0±1.0	6.0±1.0[b]	5.9±1.2[b]
eGFR (ml min 1/ 1.73m²)	56.8±38.0	38.9±37.6	38.9±42.0	39.0±26.8
Age (years)	26.0±6.8	37.3±16.0	37.5±18.0	36.8±10.6
BMI (kg/m^2)	25.2±2.6	25.8±2.8	26.0±2.7	25.2±3.3
Kidney length(cm)	10.0±1.5	10.5±1.3	10.8±1.0	10.0±2.0
Kidney depth (cm)	4.7±1.1	4.5±1.8	4.3±0.5	4.9±1.4

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Means with different superscripts (a, b) within columns are significant at P<0.05

3.5. Diagnostic performance of SWE:

When maximizing the sum of sensitivity and specificity, receiver operating characteristic curve analyses indicated that the area under the ROC curve was 0.956 (P<0.0001, 95% CI: 0.902; 01.010). The cut-off value for predicting CKD was 4.05 kPa with a sensitivity of 85.70% and specificity of 90.5%. **(Figure 4)**.

While the optimal cut-off value of SWE imaging was established to be 4.45 kPa for predicting kidney fibrosis with a sensitivity of 93.30% and specificity of 83.3%. The area under the ROC curve was 0.922 (P<0.0001, 95% CI: 0.788; 01.057) **(Figure 5)**.

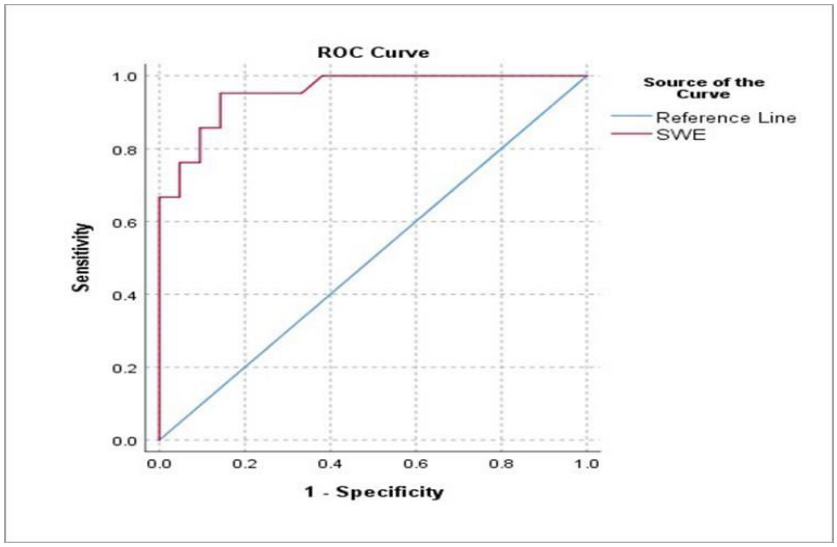

Figure 4: ROC curve of SWE to distinguish CKD from healthy kidneys, AUC = 0.956, sensitivity 85.7%, and specificity 90.5%. Cut-off value = 4.05.

ROC: receiver operating characteristic, SWE: shear wave elastography.

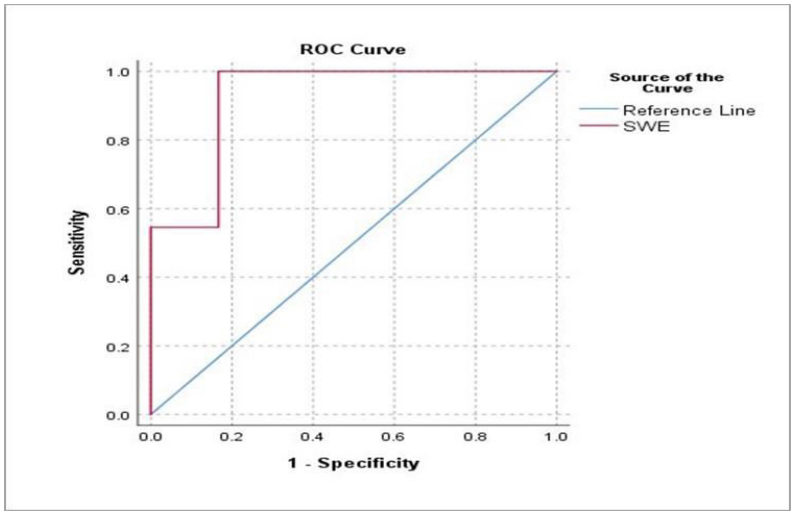

Figure 5: ROC curve of SWE for predicting kidney fibrosis. AUC = 0.922, sensitivity 93.30%, and specificity 83.3%. The cut-off value = 4.45 kPa.

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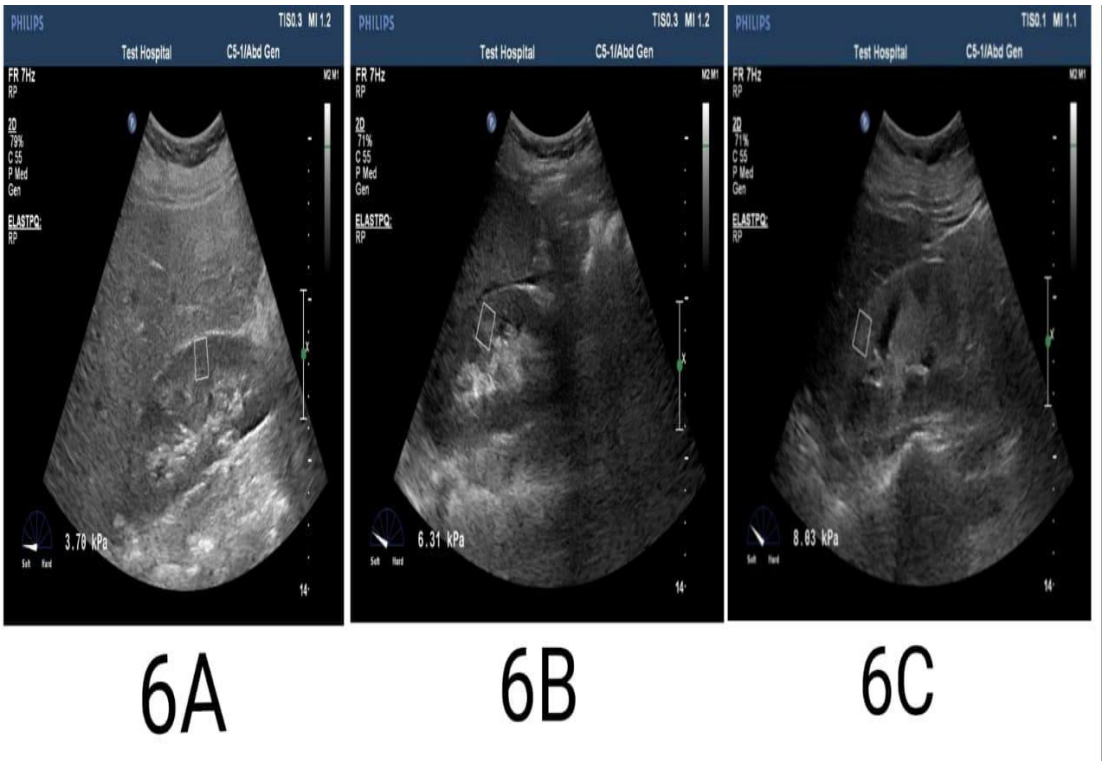

Figure 6: pSWE images of CKD patients with no (6A), mild (6B), and moderate (6C) degrees of renal fibrosis. The YM values were 3.70 kPa, 6.31kPa, and 8.03 kPa respectively

4. DISCUSSION

We began by examining the role of ARFI in differentiating between normal and CKD kidneys. Our findings indicate a favorable association between renal cortical stiffness as measured by Young's modulus (YM) values and the presence of chronic kidney disease (CKD). This was consistent with earlier ARFI studies that found a positive association between the presence of CKD and renal cortical stiffness as measured by YM Leong et al. (2018) [15] and Leong et al. (2019)[16], as well as shear wave velocity (SWV) as measured by Peride et al. (2016b)[17]. Additionally, Samir et al. (2015) [18] and Radulescu et al. (2019)[19] revealed that SWE readings in chronic kidney disease (CKD) patients were considerably greater than in healthy volunteers.

In contrast to our work, several investigations using ARFI technology on native kidneys found that SWV values were significantly lower in the CKD population than in control participants (Guo et al. (2013) [20], Hu et al. (2014) [21], and Bob et al. (2015) [22]). The explanation for this discrepancy is unknown. However, other writers suggested that in chronic kidney disease (CKD), the increasing decrease in blood flow associated with fibrosis may be the source of decreased renal tissue stiffness (Asano et al. (2014) [23] and Wang (2016)[24]). Additionally, research have been conducted that demonstrate no link between SWE and CKD (Wang et al. (2014) [25], Gao et al. (2017) [26]).Among the studies that were performed on human adult native kidneys using SWE techniques and compared between healthy and CKD patients, we noticed that the majority of the studies that used YM values showed a positive correlation between the presence of CKD and renal cortical stiffness **(Samir et al., (2015), Leong et al. (2018), Diep S (2019)[27], Radulescu et al., (2019), and Leong et al. (2019)),** apart from **Danse et al. (2017)[28]** who reported no correlation between the presence of CKD and SWE. However, most of the studies that used SWV measurements showed negative correlation **(Guo et al. (2013), Hu et al. (2014), Bob et al. (2015), and Grosu et al. (2017)[29])** or no correlation **(Wang et al. (2014), Gao et al. (2017))** between the presence of CKD and SWV measurements. The reason for this contrast is indistinct.

When comparing our results with the results from similar studies as **Leong et al. (2018) and Leong et al. (2019)** who used ARFI techniques on human adult native kidneys and used YM measurements, we noticed a significant difference between estimated YM values in both normal subjects and CKD patients. The Mean YM values in our study were 2.5±1 kPa in the control group and 3.65±0.9, 4.5±1.2,

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5.8±0.5, 5.3±1.1, and 6.6±0.9 in CKD stage 1,2,3,4, and 5 respectively with the mean value 5.44±1.4. While in the study done by **Leong et al. (2018)**, the mean YM values were 3.55 ± 1.59 in the control group and 7.61 ± 6.09, 11.61 ± 6.88, 10.06 ± 5.72, 12.75 ± 5.63 in CKD stage 2,3,4,5 respectively. Although there is a small difference between the mean YM values of the control groups in our study and the study done by **Leong et al. (2018)**, there is a considerable difference in the YM values regarding the CKD stages. However, when comparing the ROC analysis, the cut-off values of the YM measurements that distinguish healthy kidneys from those with CKD (4.05 kPa in our study and 4.31 kPa in **Leong et al. (2018))** were very close. So the higher YM values in CKD cases in **Leong et al. (2018)** could be explained by the higher number of cases included in **Leong et al. (2018)** study or may be due to the lack of standardized methodology and technique as reviewed by **Bruno et al (2015)[30], Peride et al. (2016b), and Radulescu et al. (2019).**

This discrepancy in the result occurred also in the studies that used SSI techniques and YM measurements; the YM values in **Radulescu et al. (2019)** were much higher than those of **Samir et al. (2015)**, as well as in the studies that used ARFI techniques and SWV measurements, the SWV values in **Bruno et al. (2013)** were much higher than those of **Göya et al. (2015b)[31],** despite using the same technique and studying similar population.

Moreover, in our study, a significant moderate negative correlation was observed between YM values and eGFR (r= -0.637, p<0.002). Similar results were demonstrated in **Leong et al. (2018)** (r= -0.576, p<0.0001) and **Leong et al. (2019)**, who used radiolabeled GFR measurements, (r= -0.690, p<0.0001). This strengthens the theory that the change in renal cortical stiffness could be a sign of CKD.

We found no significant difference in renal cortical stiffness between the stages of CKD except between stage 1 vs. 5 and stage 2 vs. 5. This is in agreement with **Leong et al. (2018)** who reported that there was no significant difference between CKD stages 3, 4, and 5. **Peride et al (2106b)** also reported no difference between stages of CKD. While **Bob et al (2015)** described only a significant difference between stages 1 and 2 vs. 4 and 1 and 2 vs. 5. These differences may be due to the difference in the number of subjects included in each study or the variability of the number of patients among CKD stages.

We additionally investigated the role of some potential influencing factors on SWE as age, gender, BMI, kidney length, and kidney depth. We found no significant difference in any of those studied factors between the control and the CKD groups. Among the studied factors, age was the only factor that had an association with estimated renal cortical stiffness in both healthy volunteers and CKD patients. **Peride et al. (2016b) and Leong et al. (2018)** also reported a positive correlation between age and cortical stiffness. This could be explained by the development of glomerulosclerosis, tubular atrophy, interstitial fibrosis, and arteriosclerosis with aging. However, **Samir et al., (2015)** and **Radulescu et al., (2019)** recently reported no significant correlation between YM measurements and age.

We observed that patients with renal fibrosis showed significantly higher YM values than those with no fibrosis (P<0.01). There are significantly higher YM values in cases with mild fibrosis than those with no fibrosis, but there is no significant difference between cases with mild and moderate degrees of fibrosis. This observation is supported by **Cui et al. (2013)[32]**who reported significantly higher SWE values in mild and moderate fibrosis groups than in the non-fibrosis group, while no difference between the values in mild and moderate fibrosis groups and **Venkatachalam et al. (2020)[33]** who reported higher values of SWE in patients with fibrosis than those with no fibrosis. In contrast to our study, **Wang et al. (2014)** declared that SWE measurements showed no correlation with any of the pathological indicators of fibrosis in patients with CKD. This contrast may be explained by the presence of structural heterogeneity of renal parenchyma or may be that renal fibrosis is not the only factor that affects the stiffness of the tissue at the level of the kidney as reported by **Wang et al. (2014)** or SWE measurements are influenced by the renal blood flow as described **Asano et al. (2014).**

According to the ROC analysis in our study, a cut-off 4.45 kPa was determined to differentiate between kidney fibrosis and non-fibrosis with a sensitivity of 93.3% and a specificity of 83.3%; suggesting a diagnostic reference for renal fibrosis.

When comparing our results, we found that a cut-off value of 4.05 kPa or more could differentiate CKD patients from healthy volunteers, while a cut-off of 4.45 kPa could differentiate kidney fibrosis from non-fibrosis. These close values may suggest that renal fibrosis may be a probable reason for the increase of renal cortical stiffness in CKD.

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Our study faced some limitations that should be mentioned as the small number of participants included in the study, the study was performed by one radiologist, the limited detection depth of the SWE method prevented us from recruiting obese patients and patients with hepatomegaly or splenomegaly, fixed ROI volume made us exclude patients with thin renal parenchyma from the study, holding breath was difficult for most of the patients and the sensitivity to breathing movement artifact was one of the challenges to obtain reliable measurements.

5. CONCLUSION

Our results suggest that SWE can distinguish between normal subjects and patients with CKD. SWE also can detect renal fibrosis in patientswith CKD. Despite it can`t distinguish between the stages of CKD or the degrees of renal fibrosis, it is promising in replacing the invasive renal biopsy for diagnosing renal fibrosis or at least suggesting patients who are candidates for renal biopsy. **In future studies,** we suggest including more influencing factors like renal blood supply and the influence of the SWE technique used by making a comparison between the values obtained by different techniques on the same population.

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Data Availability Statement: The data presented in this study are available on request from the corresponding author.

Conflicts of Interest: The authors declare no conflict of interest.

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