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A novel electro-Hydraulic Acoustic Therapy (eHAT) reduces blood pressure in hypertensive patients with CKD: Preliminary results

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32nd EUROPEAN MEETING
ON HYPERTENSION
AND CARDIOVASCULAR
PROTECTION

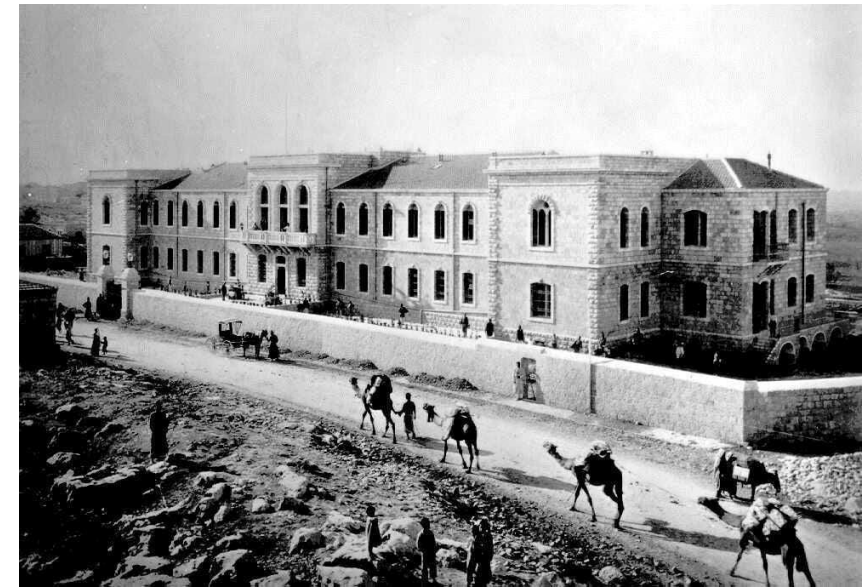
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Disclosures

I have no financial relationships to disclose concerning the content of this presentation or session



Background

- Despite advances in Medical therapy, Chronic Kidney Disease (**CKD**) and Hypertension (**HTN**) are **a growing problem**
- A novel treatment is proposed utilizing electro-Hydraulic Acoustic Therapy (**eHAT**) by **Nephrospec™**
- Animal studies have demonstrated the mechanisms, safety and potential efficacy of **eHAT**
- Preliminary clinical data demonstrates the safety and efficacy

Nephrospec™

- ✓ electro-Hydraulic Acoustic Therapy (eHAT) system , generating low intensity shockwaves
- ✓ Applicator is guided using standard ultrasound
- ✓ Targeted areas are treated by applying shockwaves with high accuracy to the desired area

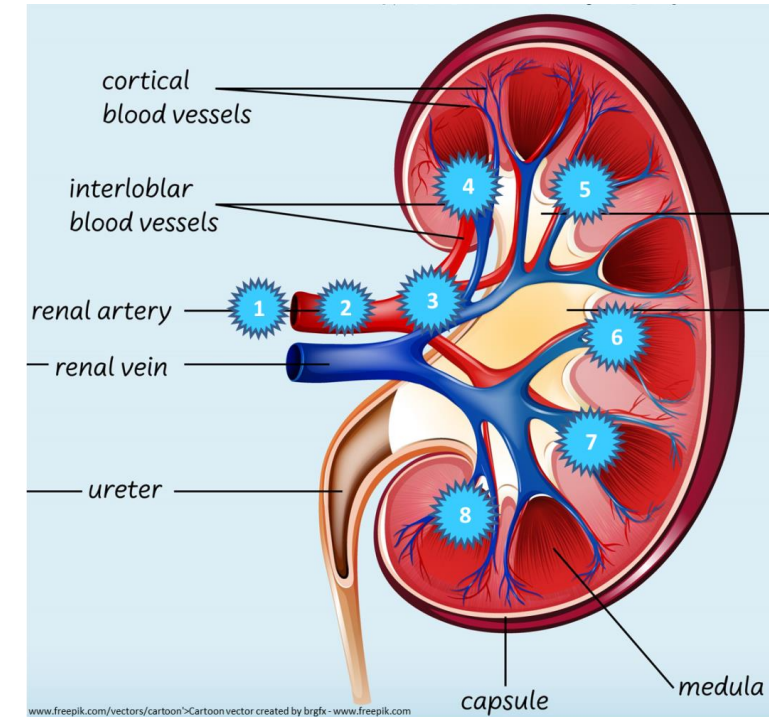
Shockwave
applicator



Shockwave
generator



Treatment



- ❖ Outpatient
- ❖ Non-Invasive
- ❖ No X-Ray Radiation
- ❖ No sedation/anesthesia
- ❖ Pain-Free

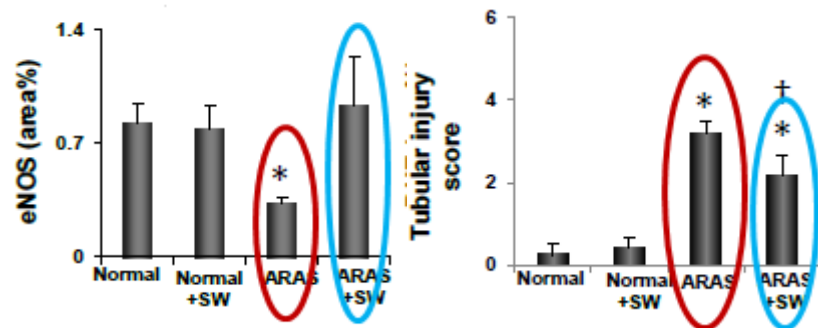
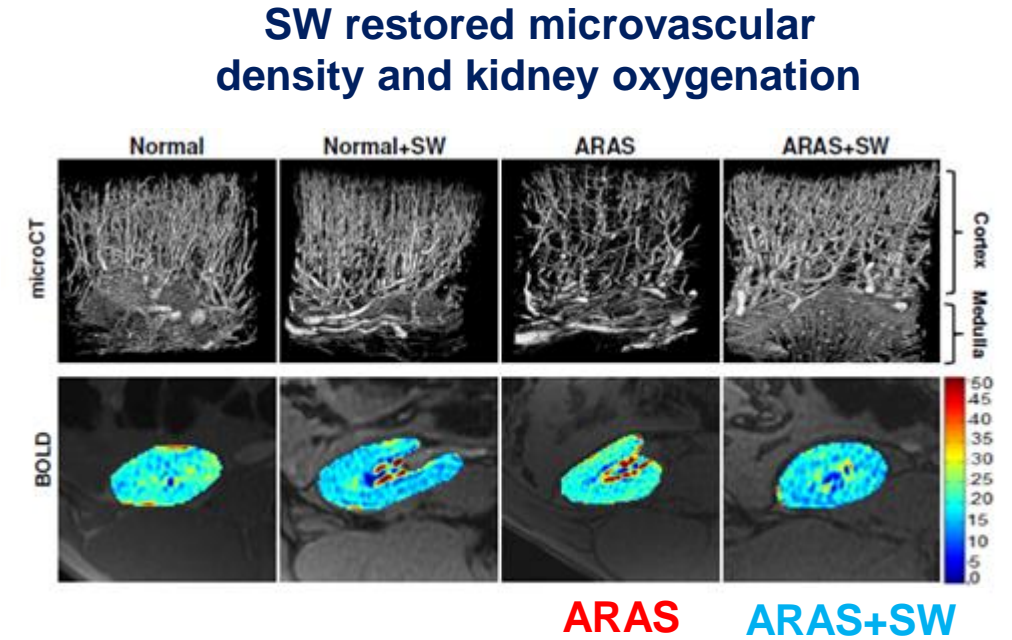
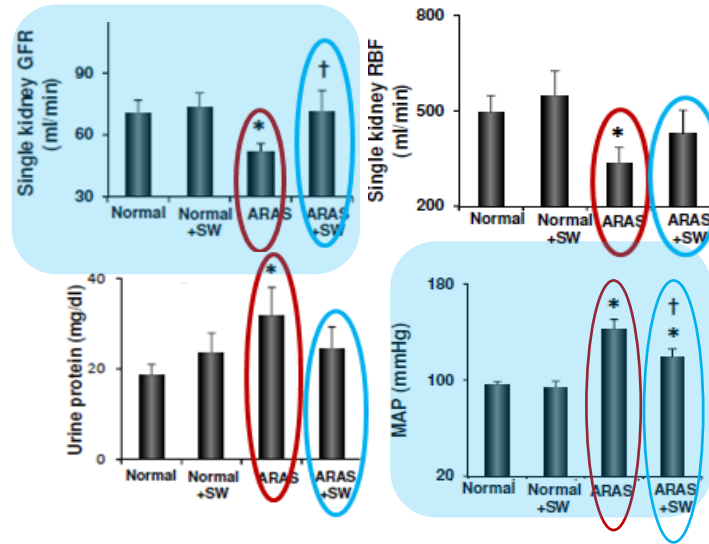


Pre-clinical and mechanism of action study

Low-Intensity Extracorporeal Shockwave Improves Renal Microvasculature in Chronic Ischemic Kidney Disease

SW Lowered Blood Pressure and Stabilized Stenotic Renal Function

RAS in pigs - RESULTS

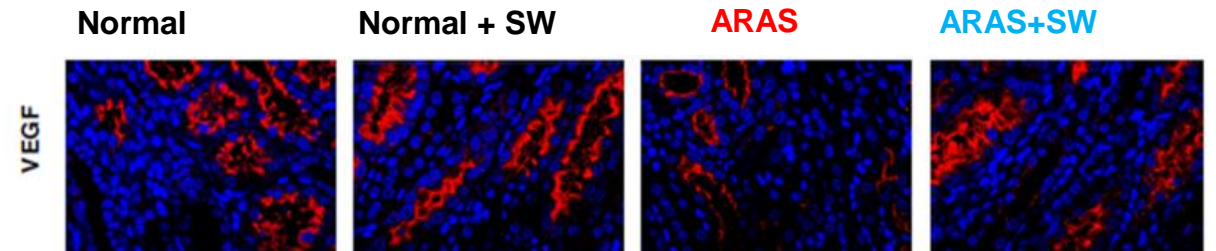


SW elevated eNOS expression in the ARAS kidney and reduced Tubular injury

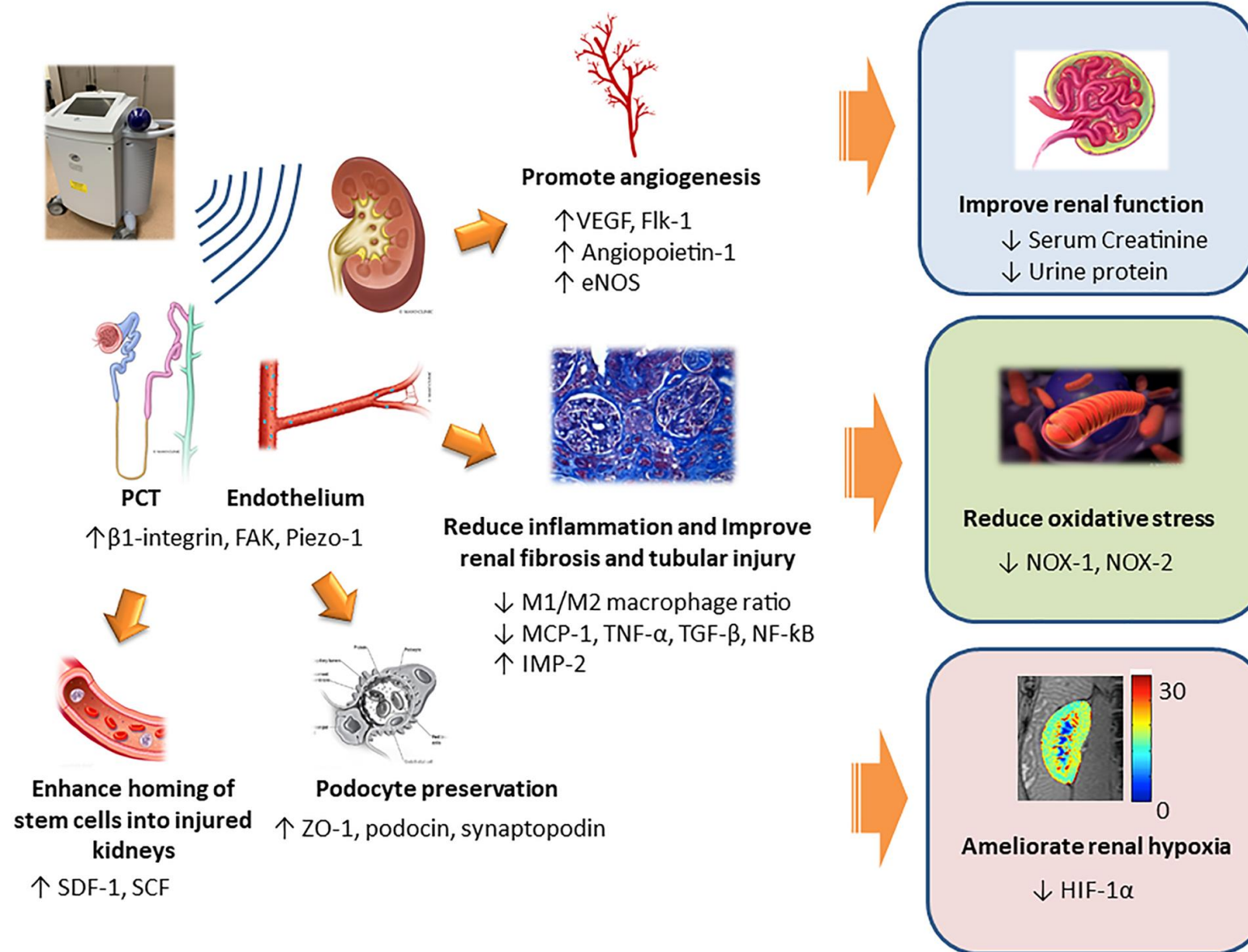
ARAS+SW

ARAS

SW increased VEGF angiogenic factor expression



Mechanisms Of Action for shockwave therapy in Kidney Repair



SZMC study

**Extracorporeal Shockwave Therapy for the
treatment of Hypertension in patients
diagnosed with Chronic Kidney Disease at
Stage IIIa/b**

The study is a single arm, prospective, exploratory study

- **OBP - Office blood pressure** was measured in a sitting position after a 5-minutes rest using a validated device at every FU
- **AOBP procedure – unattended automatic Office blood pressure** (at every FU) was measured five times (average of last three to be considered), with random intervals, in the sitting position after ten minutes of rest. readings were performed using a validated device according to the revised guidelines of the European Society of Hypertension (Stergiou, Pruijm, et al)
- **ABPM – 24-HOUR ambulatory blood pressure** (Baseline, 3- and 12-months FU)
- **eGFR** - The 2021 CKD-EPI Creatinine formula was used to calculate the estimated glomerular filtration rate

Inclusion Criteria

- Patient is diagnosed for Hypertension – BP $\geq 140/90$ mmHg
- Patient is diagnosed at stage III a/b CKD (eGFR 30-59 ml/min/1.73m²)
- On stable medical therapy

Exclusion Criteria

- Patient is diagnosed at ESRD, is on Dialysis or has had a kidney transplant performed
- Hypertension secondary to an identifiable and treatable cause
- Active Cancer – primary tumor or metastatic
- Recent (less than 6 months) history of myocardial infarction, PCI, stroke or hospitalization for heart failure
- Subjects having INR > 2.5
- Individual has type 1 diabetes mellitus or poorly-controlled type 2 diabetes mellitus (HbA1c > 10)

Primary endpoint

Improvement in BP from baseline to 12 weeks post last treatment

OR

A reduction in the dosage of medications needed to control BP

Treatment Protocol

6 treatments schedule within 3 weeks



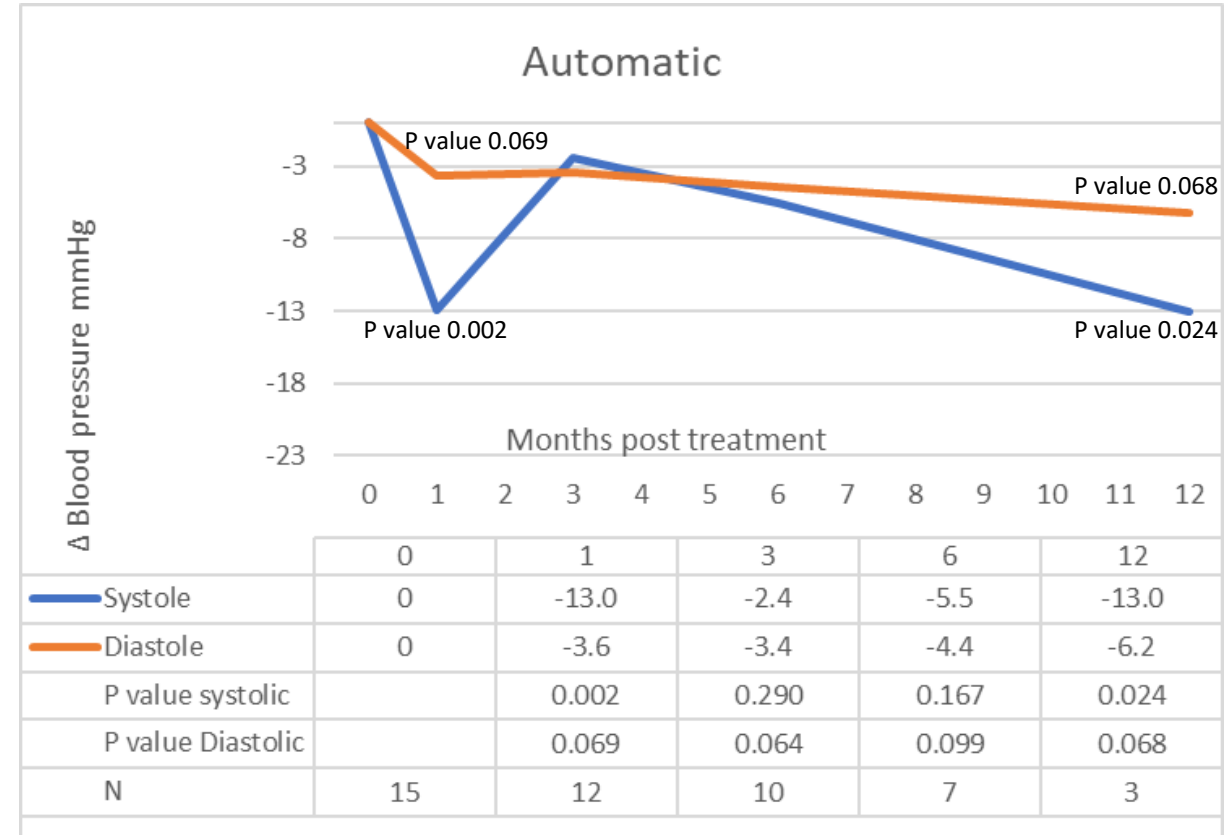
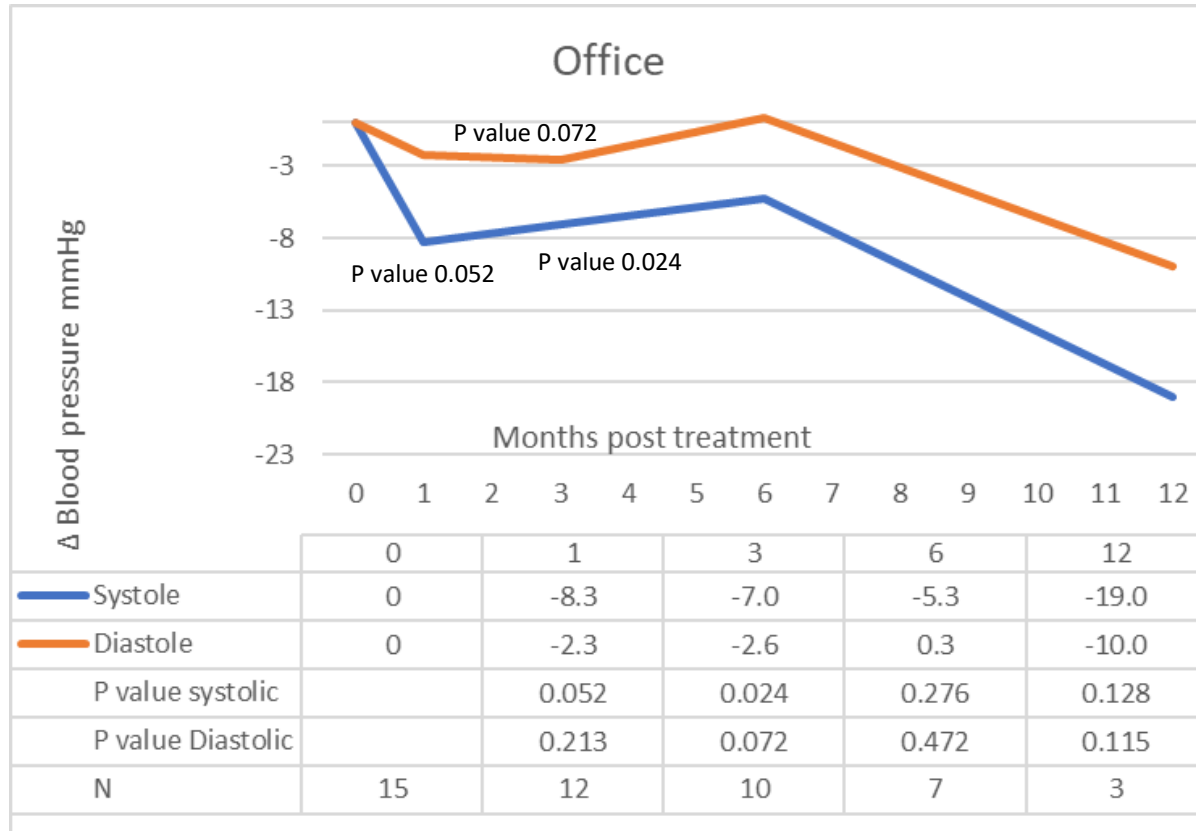
Study population (n = 19)

- Mean age: 67.5 (44-79) yrs; 7F/12M
- Diagnosed with HTN and CKD
- OBP at Baseline 137.6 (108-170) mmHg
- eGFR at Baseline 42.5 (24-67) mL/min/1.73m²

No significant side effects reported by the treated patients

Results - SZMC study

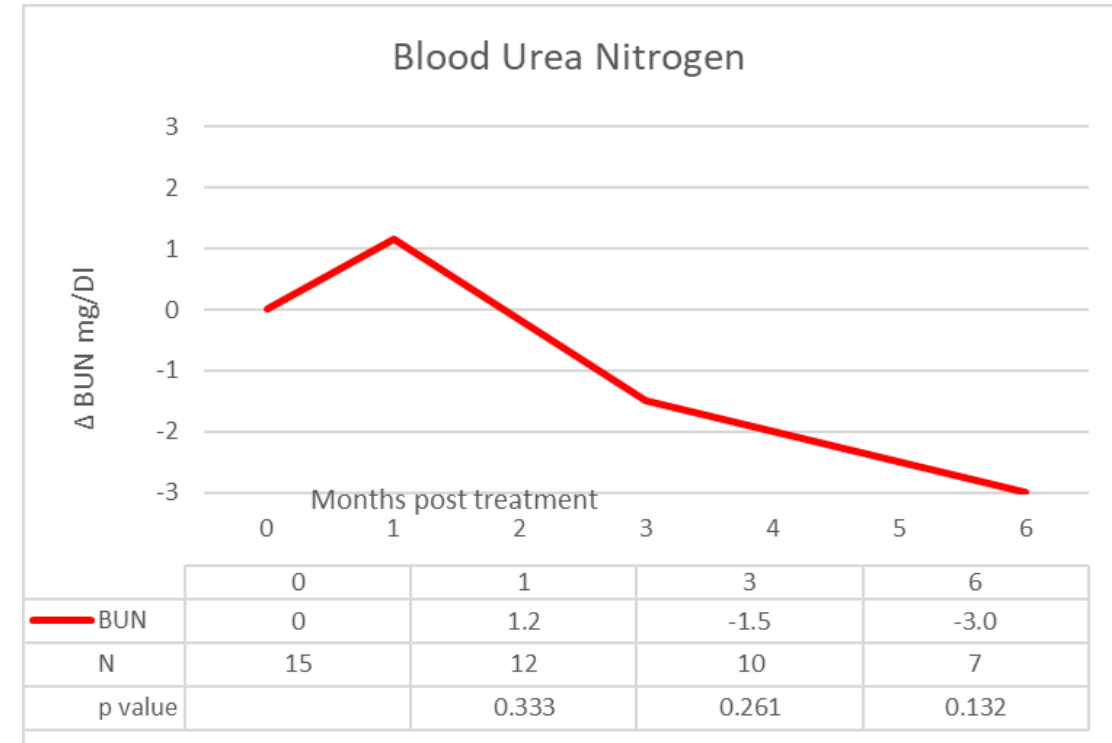
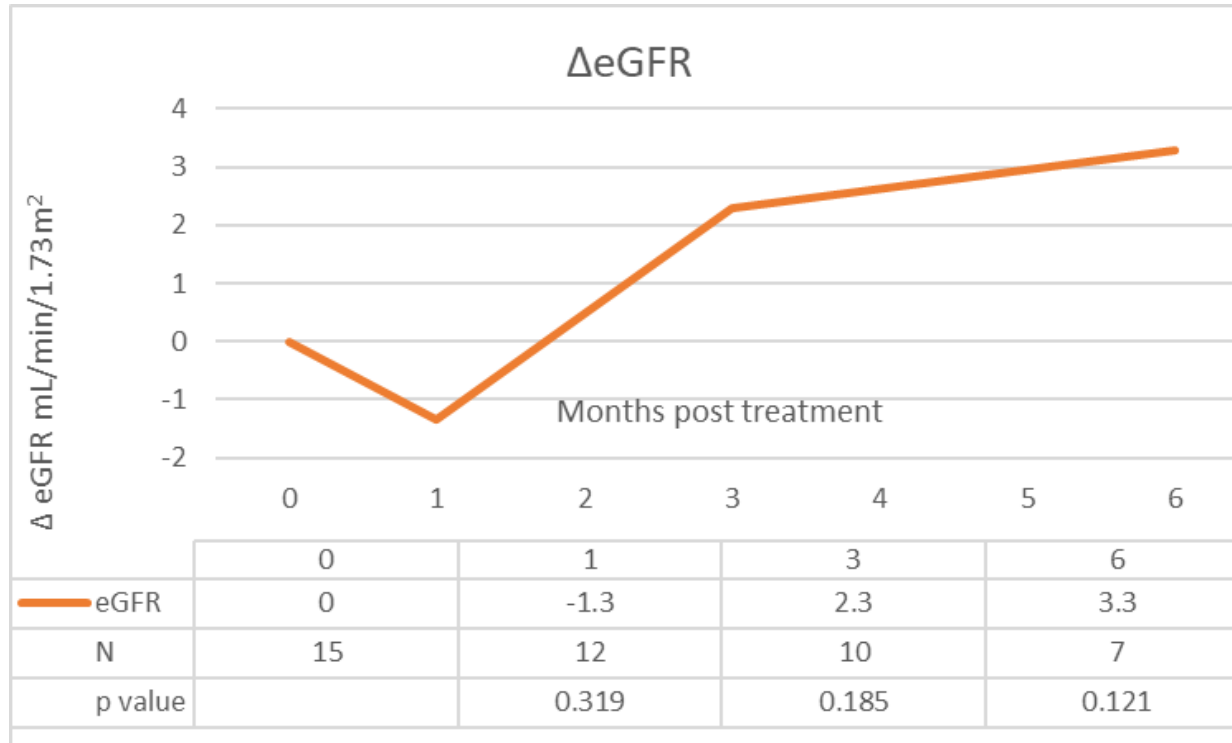
Δ Blood pressure



¹ 3 patients removed from study analysis ,initial blood pressure 115mmHg or lower

² Systolic BP results were adjusted for patients whose antihypertensive medication was reduced (reduced by 5)

Results - SZMC study – Cont.



¹ 3 patients removed from study analysis ,initial blood pressure 115mmHg or lower

² Systolic BP results were adjusted for patients whose antihypertensive medication was reduced (reduced by 5)

Conclusions

- The current data demonstrates the safety of eHAT
- Our initial outcomes suggest eHAT provides clinical benefits to patients with Hypertension and CKD
- Further larger clinical trials are needed to confirm the results of this therapy*

*Randomized controlled trials are initiated in multiple centers during the following few months