A Case of a Young Hypertensive Man with Polycystic Kidney Disease Treated with the Verve Peri-pelvic Renal Denervation Device: A Prelude to Study in CKD and Chronic Kidney Pain

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Presenter Disclosure Information

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Within the past 12 months, the presenter or their spouse/partner have had a financial interest/arrangement or affiliation with the organization listed below.

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- CSI, Stockholder;
- Spectranetics, Abbott, Medtronic, Bard, Abiomed, Honorarium and
- Medtronic, Abbott, AngioScore, Speaker
- Acist Medical Systems Grant

**Patents** -- RF, Snares, Wires, Balloon Catheters, Covered Stents, Devices for Arterial Venous Connection, Devices for LV and RV Closure
Treating Kidney Disease at the Source

TUSK
TransUreteral Sympathectomy of the Kidney
a novel device
and a 15 minute outpatient procedure
We are the only company that has described RDN pathophysiology in a human clinical nephrectomy model
The Bench-to-Bedside Transition

Limited destruction of renal nerves after catheter-based renal denervation: results of a human case study

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Preclinical-Clinical Data Results

Pre-Clinical
55 acute and chronic pigs – up to 90 days follow up
End point- 60% avg. drop in tissue Norepinephrine (marker of nerve activity)

Clinical - 14 Patients
Safety Trial - 9 pre-nephrectomy patients
No adverse effects – treatment 1 mo. prior to removal of kidney
Efficacy Trial - 4 RHTN patients
Average systolic BP drop 44 mmHg –immediately post treatment
Efficacy Trial - 1 ESRD dialysis patient
14 mmHg systolic BP drop at 60 days post treatment
Reduction of blood pressure medications from 5 to 2
Clinical Trial
Safety

• Pre-nephrectomy
  9 patients
• Procedure - one month prior to surgery
• After procedure-Explanted kidney
  H&E and Immuno-histochemistry
Pelvis Wall - Distal to Ablation Zone (Control)

- Transitional epithelium
- Lamina propria
- Smooth muscle
- Renal Pelvic Space
- Serosa

Arrows indicating various structures and locations.
The nerves (N) are located within 1 mm of the pelvic space and adjacent to the treatment area.
The bulk of the nerves (N) are located less than 1 mm deep in the treatment zone (red).
Clinical study
Resistant hypertensive patient

**Efficacy**

- 4 patients resistant hypertension
- 2 or more drugs
- Ave BP 170/94 mmHg
- General Anesthesia
- 1 Mo Follow-up
India Clinical Trial Results RHTN

![Graph showing blood pressure results](image-url)

Baseline Systolic Blood Pressure: 172 mmHg
1 mo. post-tx. Systolic Blood Pressure: 128 mmHg

Baseline Diastolic Blood Pressure: 94 mmHg
1 mo. post-tx. Diastolic Blood Pressure: 81 mmHg

(44) mmHg reduction in systolic blood pressure
(13) mmHg reduction in diastolic blood pressure
## Verve Phoenix Clinical Trial
### 4 Ball Efficacy Summary

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A 27 year old hypertensive Indian male presented with polycystic kidney disease and a large pelvic stone necessitating nephrectomy
THE SYSTOLIC BP DROPPED 24MMHG WITHIN 20 SECONDS AND WAS MAINTAINED AT THIS LEVEL UNTIL NEPHRECTOMY
Major Global Problem

13.4% of the world population has CKD

U.S. Statistics

49 Million people have chronic kidney disease

490,000 are on dialysis

Life expectancy on dialysis < 5 years

Each year Kidney Disease kills more people than breast or prostate cancer- 47,000 in 2013

Orphan disease with no treatment options
Kidney nerve anatomy

Afferent nerves originate in the collecting system
Treating Kidney Disease at the Source

Chronic Pain in CKD

- 70% of pre-ESRD patients have chronic pain
- ~ 50% of ESRD have chronic pain
- ~ 80% of polycystic kidney disease patients have chronic pain...only treatment option can be nephrectomy
Chronic Kidney Disease Pain Market Opportunity

• Severe Pain Market – Replacing Opioids
• 30% of all CKD patients = 14.7 Million patients
• 20% Market penetration (5 years) 2.9 Million Procedures

$7.2 Billion Opportunity
Review

Early Adaptation
Nephrologists understanding of the disease
Urologist need for new procedures

Technical Feasibility
Urologist has been using RF energy > 50 years

Financial Burden
Outpatient/ Office setting
Attractive to third world and developing countries

CKD
Huge burden to the healthcare system
with no treatment options
Commercialization Potential

NEPHROLOGY

75% of resistant hypertensive patients are managed by nephrologists…only 12% by cardiologists
A New Treatment for Chronic Kidney Disease: Denervation in the Collecting System with the Verve Medical Device

• If you are one of the 50% of us with hypertension, would you like to...
• Take a drug or drugs for the rest of your life?
• Would you like to have a one time procedure that would be done with no contrast in a doctor’s office in 15 minutes
Remember a 2mmHg decrease in mean SBP results in a 7% reduction in CVD mortality and 10% reduction in stroke mortality.

The Value of Verve

• Orphan disease with an unmet clinical need
• Massive and expanding markets
  $ 36 Billion Pain/$96 Billion CKD/$400 Billion HTN & Diabetes
• Proprietary technology / Intellectual Property
• Experienced management team: Medical Devices & Clinical Specialty- Nephrology/Urology