## **Prospective Cohort Study**

Effectiveness of Gravitational Resistance and Diet (GRAD) system in reversing chronickidney disease (CKD) - among dialysis patients.

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## **Highlights:**

- 1. The pioneering cohort study to assess the effectiveness of GRAD system in reversing CKD among dialysis patients.
- 2. Gravitational resistance and DIP diet<sup>1</sup> were utilized in the GRAD System as the main tools to help patients reverse CKD (Chronic Kidney Disease).
- 3. Head Down Tilt (HDT) and Hot Water Immersion (HWI) were <u>used to induce gravitational</u> resistance<sup>2</sup>.
- 4. 100 Dialysis patients formed the sample study group and were assessed and recorded on a variety of parameters for an average of 100 days.
- 5. Among the patients who adopted GRAD system fully, 75% were relieved from having to undergo Dialysis and 89% ould free themselves of full or partial dependence on drugs.
- 6. Quality of life improved and economic burden reduced among 100% of the patients who followed the GRAD System.

## **ABSTRACT:**

**BACKGROUND:** The global prevalence of Chronic Kidney Disease (CKD) referred to as *mutraghat*<sup>7</sup>/*mutrakshay* in Ayurveda is nearly 70 crores<sup>3</sup>, with nearly 1/3<sup>rd</sup> of the patients belonging to either India or China. There has been no lasting and effective cure till now, and the only available treatments are either Dialysis or Kidney transplants.

**OBJECTIVE:** The objective of the Study was to determine the effectiveness of the GRAD System developed by Dr. Biswaroop Roy Chowdhury in reversing CKD among the patients who are dependent on Dialysis.

**METHODS**: This was a prospective cohort study conducted from August 2021 to March 2022. 100 dialysis patients, who agreed to adopt GRAD system in their lifestyle for an average of 100 days were closely monitored and data on various parameters carefully recorded. Data was collected using interviewer-administered questionnaires, examination of participants, and review of medical records.

**RESULTS**: 28 out of 100 dialysis patients fully adopted the GRAD system. Among them, 21 (75%) were completely free of dialysis and supporting drugs while the remaining 25 % were partially free of dialysis and supporting drugs.

72 patients partially adopted the GRAD system. Among them,11 (15%) were able to be free of all the supporting drugs while all (72) could reduce the frequency of dialysis. Quality of life improved among 100% of the patients and their economic burden reduced from 70% to 90% in 58% of the patients. There was no serious negative impact seen and no death or adverse event was reported as a result of the adherence to GRAD System. IN fact, all the patients experienced a marked improvement in their

**CONCLUSION**: GRAD system can be recommended as an effective method to reverse CKD among mild,

moderate, and severe CKD patients and can be seen as an effective alternative to dialysis and kidney

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Chronic Kidney disease (CKD) referred to as *mutraghat*<sup>7</sup>/*mutrakshay* in Ayurveda is a lasting condition all over the globe.

Until now, there had been no known intervention scientifically proven to help severe CKD patients to reverse the disease and free themselves of their dependency on dialysis, transplant and drugs. However, in the modern scientific literature there are references of Head Down Tilt (HDT) and Hot Water Immersion (HWI) which are known to activate the kidney. These techniques can also effectively excrete Sodium by five times, Potassium by up to three times, increase the urine volume by three times and result in the overall reduction of body weight and swelling<sup>6</sup>. Even in Ayurveda (*ch.su/14/44-45*) as an effective method to rejuvenate the compromised kidneys.

## **Need for the Study**

Chronic renal failure (CRF) is a progressive, irreversible decline in renal function that occurs over time. The only symptom is a metabolic anomaly at first. When the glomerular filtration rate (GFR) falls below 30 ml/min, CRF is evaluated. The traditional management method comprises dialysis and kidney transplantation, both of which are out of reach for the Indian populace due to financial constraints. As a result, research into a safe and alternative therapy that can assist reduce the need for dialysis and delay the need for kidney transplantation is required.

An average kidney transplant costs Rs 200,000 in a government hospital and Rs 400,000 in a private facility. In addition, the annual medicine maintenance cost after the transplant is Rs 200,000 per year, or Rs 20,000 per month. As a result, the social and economic ramifications of CRF are significant, and the traditional therapeutic method comprises dialysis and kidney transplantation, both of which are unaffordable and unacceptable to the Indian people. As a result, research into a safe and alternative therapy that can assist reduce the need for dialysis and delay the need for kidney transplantation is critical. Several institutes and academics are attempting to make progress in this approach.

Dr Biswaroop Roy Chowdhury combined HDT, HWI and the DIP diet to develop a protocol called the GRAD System, with the goal to reverse kidney failure, especially among the patients who are dialysis dependent.

## Objectives and goals of the Study

✓ To demonstrate the effectiveness of the combination of various techniques and Ayurvedic remedies in the treatment of CRF.

- ✓ To provide scientific support for findings that suggest that specific therapies or their combination thereof can effectively correct albuminuria and serum creatinine values, which are key hallmarks of CRF, as well as enhance renal function as seen by lower serum creatinine and blood urea levels.
- ✓ To provide a future therapeutic option for a large human population suffering from CRF, with the goal of minimising the need for HD and avoiding or delaying kidney transplantation.

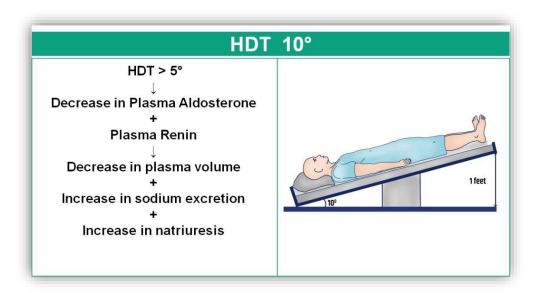
## **Methods and Techniques**

2 hours of HDT + 2 hours of HWI + DIP Diet = GRAD System. As part of the GRAD system, dialysis patients are encouraged to do 2 hours of HDT and HWI every day along with following the DIP Diet. Every day for the purpose of monitoring the patient's *PRAN* (Patients Reporting to Activate Nephrons) sheet is being maintained for each of the patients through the GRAD app. In PRAN sheet following parameters are being mentioned.

Weekly PRAN Sheet (For Kidney / Liver Patients) Arrow represents the expected outcome of the patients on GRAD system						
Date	B.P.	Pulse	↓Weight	Swelling (yes/no)	Urine Output (If <400 ML)	Symptoms
1	HDT	HDT	HWI	HDT		
	1. 2.	1. 2.	1. 2.	1. 2.		
	HWI 👃	HWI	HWI	HWI		
	3. 4.	3. 4.	3. 4.	3. 4.		

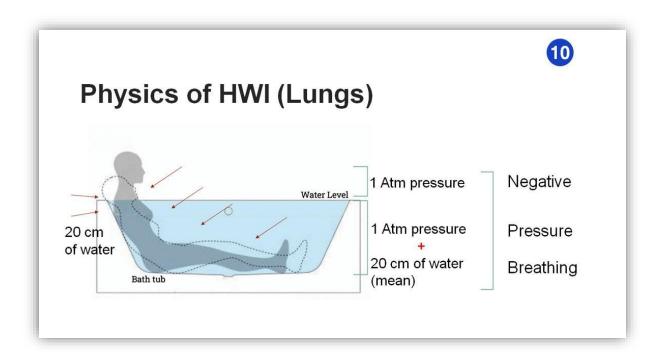
Based on the improvement on the above parameters, the patients who participated in the study were required to taper down or phase out the drugs and various other medications which they were taking and to reduce the frequency of dialysis. Patients were advised to gradually increase the duration of HDT/HWI as the body adapted to the therapies and started showing positive improvement. Many patients could adhere to the GRAD system partially because of poor family support, lack of discipline or because of discouragement from their dialysis centers or other reasons.

WHAT IS Head Down Tilt (HDT)<sup>6</sup>



When a patient is made to lie down at 10 degrees angle of the head, it leads to a decrease in the Plasma Aldosterone and Renin hormones in the body. This results in a decrease in Plasma volume and subsequently, an increase in natriures is or sodium excretion from the body.

## WHAT IS Hot Water Immersion HWI (AVAGAH SWED<sup>8</sup>)



## The Physics of HWI (Lungs)<sup>10</sup>

When a patient is made to sit in the bath tub with water level up to the neck, the air pressure above the neck is 1 Atmosphere. Below the neck the atmospheric pressure is 1 Atmosphere. If the mean height of the water in the bath tub is 20 cm, the pressure below the neck increases by about 2% (1 atm + 20 cm).

Therefore, when a patient sits in neck deep water, his body undergoes two different pressures, one above the neck and one below the neck. This difference in pressure results in negative pressure breathing.

As a result of this breathing, a 20% increase in the stroke volume of the heart is observed. The heart pumps an increased volume of blood by 20% due to the negative pressure breathing.

This increased blood pumping leads to redistribution of blood from the lower portion of the body to the upper torso, waist upwards.

# **HWI Causes Dialysis**



13

- Sodium Excretion 5 Times
- Potassium excretion doubles
- Urine volume increases three times
- ■Weight / swelling reduced

## Chemistry of HWI<sup>12</sup>

As shown in image, the movement of the blood from being centred on the kidney upwards esults in certain chemical changes in the body. The levels of IL-6, Ilira, Hsp72, 1Hsp72, andNO increase in the body whereas the levels of Norepinephrine, Vasopressin, and Renin decrease in the body within two hours of immersion of the body in the bath tub.



## **HWI Causes Dialysis**



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- Potassium excretion doubles
- Urine volume increases three times
- Weight / swelling reduced

## What is D.I.P Diet

The D.I.P (Disciplined and Intelligent diet) is being developed by Dr Biswaroop Roy Chowdhury and through clinical trials and various case studies, it has been proven to be effective in reversing life style diseases.

## STEPS TO DESIGN YOUR PERSONALIZED D.I.P. DIET:

## Step-I

Till 12:00 noon, eat only fruits of three to four types including mango, banana, grapes, etc.

Minimum amount to be consumed = Your body weight in kg  $\times$  10 = .... gm

For example, a 70 kg person should consume at least 700 gm of 4 types of fruits before 12 noon.

## Step-II

Always eat your lunch/dinner in two plates. Plate 1 and Plate 2

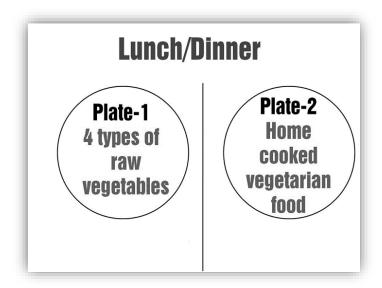


Plate 1 should consist of four types of vegetables like carrot, tomato, radish and cucumber etc. in raw form. Minimum amount in Plate  $1 = \text{Your body weight in kg} \times 5 = \text{gm}$  For example, a 70 kg person should eat at least 350 gm of four types of raw vegetables. Plate 2 should consist of home cooked vegetarian food with negligible salt and oil.

First finish eating from plate 1 in accordance with the above calculation, then take from plate 2 as much as you want. The rules for lunch and dinner are the same; however, you must remember to finish dinner by 7:00 P.M.

## Step-III

## To Avoid **Snacking / Binge eating** 1. **Soaked nuts:** Your wt(kg) =. 1. Packed food (eg. 70 kg person can consume 70 gm of nuts 2. Refined food in aday) 3. Dairy food/Animal foods 2. Fruits: Plenty 4. Nutritional supplements 3. Coconut water: As you like 4. **Sprouts:** Your Wt.(kg)= gm 5. Avoid drinking 5. Coconut: As you like tea/coffee specially 6. Sunshine: 45 min before lunch 6. Never eat after 8:00 P.M. 7. NSAIDs

## Ayurvedic perspective of CRF and Hot Water Immersion (HWI) And Ayurveda's relationship with GRAD System

## *Vrukk* <sup>9</sup>or Kidneys in Ayurveda

Nirukti "वर्षति इति वक्: क" (अमरकोर्)

The word derived from the word "वषृ सेचने" which means Irrigation.

"बकु" word is also used for vrukka (अमरकोष).

Functions "वक्: कौ स्ुटटकरौ प्रक्िौ जठरथिथय मेदस्" (शा॰ स॰ ५/८४)

The human body and its nutritional element which is food or both derived from a combination of 5 elements (*Mahabhutas*). The various permutations and combinations of these five foundational elements of food and the body can be process of modified adapted or incorporated or eliminated to cause remedy or prevent certain conditions from arriving in arising in the body. This can then be transformed as *sajitha* or tissue in which specific substances or *Dutt wahrasa* (specific nutrients) can be incorporated for boosting *sharir dhaatus*.

*Vrikk* or Kidney is made up by *rakht* and *meda*, and is the end part of *Ahaarpaak*. The anatomical *Vrikk* is an organ and can be used to refer to the Renals, Suprarenals, Ureters and bladder in different contexts. *Vrikk* is the supplementary organ of *koshtha* and are located in the *koshtha*. *Vrikk* (Kidneys) and *Mutra Vaha Strotas* (Urinary Tract) or Nephrons are micro channels for the production and storage of urine<sup>1</sup>.

## Pathogenesis (Samprapti) of CRF/Mutraghat in Aurveda

According to Ayurveda, Chronic Kidney Disease(CKD) resembles *Mutraghat/ Aama* in *Mutra vaha Strotas* that hampers the function of kidney. *Dosha Vata* and *Kapha* are mainly involved in it.

## Mutraghata

- •Sushruta Samhita Uttaratantra -58. (Mutraghata Pratishedha Adhyaya)
- Charaka Samhita Siddisthana 9 (Trimarmiya Siddhi Adhyaya)
- Ashtanga Hridaya Samhita Nidanasthana-9 (Mutraghata Nidana Adhyaya)
- Ashtanga Hridaya Samhita Chiktsasthana-1 1 (Mutraghata Chikitsa Adhyaya
- Madavanidana-3 1 (Mutraghata Nidana Adhyaya)

## MUTRA-KSHAYA Dehydrated and fatigued.

**Pathogenesis**:- Even though a *Ruksha* person has no *Pitta* aggravating factors, but *Pitta* along with *Vata* has been stressed upon. This leads to still the involvement of the drying up of the urine. :- (Su. Utt. 58/17; Ch.Si.9/34; A.H.Ni.9/37)

## Mutrashoshana - Clinical features:

Burning micturation, painful micturition, troublesome small quantity of urine Da.Su.Utt.58/17)

## Treatment of Vrukk Dosha mentioned in Charak and Susruta Samhita

<sup>1</sup> reference. Sushruta Samhita, Nibandhasamgraha commentary of Dalhana, Nyayachandrika commentary of Gayadasa, edited by Yadavji Trikamjee Acharya and Narayan Ram Acharya, Chaukhamba Orientalia, Varanasi, Reprint, 2009; 386

## Awagah Sweda

Ayurvedic therapy or its incorporation or combination with other kind of therapies is primarily aimed and the maintenance of the **Homeo stasis** in the system by eliminating the excess or undesirable elements and aiding in the absorption of the essential elements by the body.

Charak Samhita mentions the inclusion of Awagah Sweda as an effective treatment.

वातहरोत्काथक्षीरतैलघृतपिशितरसोष्णसलिलकोष्ठकावगाहस्तु यथोक्त एवावगाहः॥४५॥ vAtaharotkvAthakShIratailaghRutapishitarasoShNasalilakoShThakAvagAhastu yathokta evAvagAhaH॥45॥

Fomentation by immersion in a tub filled up with <u>vata</u> alleviating decoctions, milk, oil, ghee, meat juices or hot water is termed as *avagaha*. [45]

## **Sutra Sthana Chapter 14**

Indications of swedana

प्रतिश्याये च कासे च हिक्काश्वासेष्वलाघवे। कर्णमन्याशिरःशूले स्वरभेदे गलग्रहे॥२०॥ अर्दितैकाङ्गसर्वाङ्गपक्षाघाते विनामके। कोष्ठानाहविबन्धेषु मूत्राघाते विजृम्भके॥२१॥ पार्श्वपृष्ठकटीकुक्षिसङ्ग्रहे गृध्रसीषु च। मूत्रकृच्छ्रे महत्त्वे च मुष्कयोरङ्गमर्दके॥२२॥ पादजानूरुजङ्घार्तिसङ्ग्रहे श्वयथाविष। खल्लीष्वामेषु शीते च वेपथौ वातकण्टके॥२३॥ सङ्कोचायामशूलेषु स्तम्भगौरवसुप्तिषु। सर्वाङ्गेषु विकारेषु स्वेदनं हितमुच्यते॥२४॥

It is said that <u>swedana</u> is useful in rhinitis, cough, hiccups, breathing difficulties, heaviness of body, earache, headache, cervical pain, hoarseness of voice, choking sensation of throat, facial palsy, monoplegia, quadriplegia, hemiplegia, prostrated postures, abdominal flatulence, constipation, urinary retention, excessive yawning, stiffness of flanks, dorsum, lumbar and abdomen, sciatica, dysuria, scrotal enlargement, body ache, pain and stiffness of dorsum of foot, knee, thigh and calf, edema, severely painful radiculopathy, indigestion, chills and shivering, subluxation of ankle, contractures, convulsions, colicky pains, stiffness, heaviness and numbness, and such disorders anywhere in the body. [20-24]

सङ्करः प्रस्तरो नाडी परिषेकोऽवगाहनम्। जेन्ताकोऽश्मघनः कर्षूः कुटी भूः कुम्भिकैव च॥३९॥ कूपो होलाक इत्येते स्वेदयन्ति त्रयोदश। तान् यथावत् प्रवक्ष्यामि सर्वानेवानुपूर्वशः॥४०॥

Thirteen varieties of fomentation are *sankara*, *prastara*, *nadi*, *parisheka*, *avagahana*, *jentaka*, *ashmaghna*, *karshu*, *kuti*, *bhu*, *kumbhika*, *kupa*, and *holaka*. They are further detailed accordingly in the same sequence. [39-

The 13 varieties of Saagni Sweda include Avagaha.

Avagah *swedana* /*Sudation* is classified as *Saagni Sweda* because it uses heated fluids that have been prepared with medicines only after coming into touch with heat or fire (by heating or boiling on fire)

Material for avagaha sweda (tub fomentation)

एत एव च निर्यूहाः प्रयोज्या जलकोष्ठके। स्वेदनार्थं घृतक्षीरतैलकोष्ठांश्च कारयेत्॥३४॥

These same decoctions can be used in a water tub for fomentation. In a similar manner, *ghee*, milk, and sesame oil may also be used in tub fomentation. [34]

Abhyanga (herbal oil massage) with Vatahara tailas is administered to the individual (patient) who would get Avagaha Sweda (oils which alleviate vitiated vata). Later, he is forced to sit in a large tub that is large enough to fit him. He should sit in the tub with his neck and head above the water's surface. Fill the tub halfway with hot vatahara dravas (liquids having vata alleviating property). These liquids might be any of the following:

*Vatahara Patra Kwatha* — water-based decoctions created by ingesting and processing leaves with *vata*-relieving properties.

Vatahara Siddha Ksheera is milk that has been treated with vata-relieving decoctions.

Taila is a kind of oil that is used to treat a variety of ailments. Ghrita is ghee that has been medicated.

Mamsarasa is a kind of soup.

Ushnodaka – warm water, and so on

## Here warm water was used for giving HWI

Avagaha sweda can also be made using *Siddha Jala* – water that has been prepared with herbs. This decoction is not made the usual way; instead, the water is just boiled with the herbs. The following are some examples of *Siddha Jala*:

#### **Duration of time**

According to the necessity and condition, *Avagaha Kala - Avagaha Sweda* should be administered for 1 *muhurta* (48 minutes) to 4 *muhurta* (192 minutes). Alternatively, sudation should be performed until the patient begins to sweat appropriately and exhibits signs and symptoms of proper *swedana*, as per the basic concept of *Swedana*.

## Practise of HWI or Avgasveda in History

Hot water Immersion has always been an inherent part of daily life in almost all parts of the world. The practice of immersing in water has been such a fundamental ritual that it has even permeated into the daily lives of people as a ritual, spiritual exercise, stress busting technique, sanitary and hygienic practice et al. t has been imbibed in a daily ritual and practices as part of religious rituals<sup>2</sup>.

Historical references indicate that Hot Water treatment has been an inherent part of Indian as well as European culture since times immemorial. It has been prevalent in nations, cultures and almost all ancient civilizations have the tradition of having a communal bath in which people use to go and immerse themselves in Hot, Cold or normal water. This is true of the Indus valley civilization where the Great Bath at Mohenjo daro and at all significant other sites are notable examples. The Sumerian civilization, Egyptian civilization as well as the Greek and Roman civilizations attached great importance to the bathing rituals.

In Ayurveda also, HW I treatment or Avagah sweda has been prevalent in India since ancient times as evidenced by the finding of communal baths which have existed down the ages. Almost all the cities of the Harappan civilization, Ancient Rome, Babylon, Greece or Egypt and Persian Civilisations had Communal Baths or *Hamams* that have been frequently in use in Europe from ancient times to the medieval ages. Bathing in hot tubs was an important weekly ritual done before

going to church on Sunday for the sanitary and health related benefits.

In India this practice was incorporated in Ayurveda as Awagah sweda.

## Study site and participants

GRAD study on Dialysis patients is a prospective cohort study on the patients who are currently reliant on dialysis. 100 Dialysis patients from across the country, who adopted the GRAD system (either fully or partially) were observed for an average 100 days from August 2021 to March 2022. 24% of the patients visited the Hospital and Institute of Integrated Medical Sciences (HIIMS) located in multiple locations of Dera Bassi, Punjab and Jaipur/Jodhpur, Rajasthan along with their family members to get the training on the GRAD System. The remaining 76% patients underwent online training through videos on implementing the GRAD System at home. 100 patients were located across 22 states with majority of the patients belonging to Delhi, Punjab, Haryana, and Rajasthan.

## **INCLUSION CRITERIA:**

- 1. Patients who were on dialysis at least once a week.
- 2. Patients who were willing to adopt the GRAD System.

#### **EXCLUSION CRITERIA:**

- 1. Patients not on dialysis.
- 2. Patients who discontinued following the GRAD system.
- 3. Patients who did not cooperate to share their daily progress report in accordance to PRAN sheet.

## **DATA COLLECTION:**

- 1. At the selection stage, patients were asked to fill the Diet and Medication (DAM)) form and submit all relevant medical reports including KFT, 3 days of Blood pressure and blood sugar (if diabetes patients) and other relevant blood reports. (The form is attached as Annexure 1)
- 2. Subsequently, daily/weekly data were collected in accordance with the PRAN sheet. Various modes were used to monitor and collect the data, including telephonic calls, video conferencing, and also through a customized GRAD App. In addition to the PRAN sheet, the following information was also collected:

Weakness Scale (0-10)
Vomiting
Itching
Delirium
Seizure
Expenses (Dialysis/ Care Taker/ Medicines/ Transport/ Doctor
Which Date Dialysis Stopped
Which Date Stopped Partially
Since When MEDICINE Stopped Partially
Since When Medicines Stopped Completely

Since When Medicines Stopped Completely
Since When Medicines Stopped Completely
Would you recommend this to others?

During the entire period of study, the patients were motivated to follow the GRAD system as closely and accurately as possible. They were also encouraged to share the relevant data including daily urine output, blood pressure, weight and any discomfort /symptoms on real time bases either through GRAD app or through telephonic conversation.

## **Ethics Statement:**

The participants submitted informed consent in writing expressing their willingness to participate and adopt GRAD System. In the case of minors (04,) their guardians and caretakers signed the consent form. Withdrawal from the study never jeopardized the participants' health.

## **Evaluation of study participants**

Trained research assistants obtained informed consent before participants were enrolled into the study. Demographic information was collected through interviews and responses were collated and assessed on a questionnaire. This included age, gender, education, employment status along with lifestyle behaviors such as alcohol use, cigarette smoking, physical activity levels, frequency and quantity of daily fruit and vegetable consumption, and table salt intake. A detailed medical history including duration of CKD diagnosis and doses of medications being taken at the beginning of the study were also obtained.

## Representation of the demographic profile of the patient group under study

	Gen	der	
Age	Female	Male	Total
15-20	2	2	4
20-25	1	3	4
25-30	3	1	4
30-35	2	3	5
35-40	4	9	13
40-45	5	14	19
45-50	7	7	14
50-55	3	6	9
55-60	3	5	8
60-65	1	2	3
65-70	1	9	10
70-75	2	0	2
not available	1	4	5
Total	35	65	100

Anthropometric evaluations including measurement of weight and height were recorded. Body Mass Index (BMI) of each participant was then derived by dividing the weight and height in meters.

## **Data Analysis:**

Data of 100 eligible patients was collected with an average monitoring duration being 100 days. The data is divided in 2 groups:

## Group 1: Patients who followed GRAD system fully. Criteria of 100% adherence to GRAD system:

- 4 hours of HDT + HWI for more than 80% of the monitoring days.
- Following 100% DIP diet for more than 90% of the monitoring days.

## **Group 2**: Criteria of partial adherence to GRAD system:

- 4 hours of HDT + HWI for less than 80% but more than 50% of the monitoring days.
- Following 100% DIP diet for less than 90% but more than 50% of the monitoring days. Based on the above criteria only 28 participants were eligible in group 1 and 72 participants were eligible in group 2.

Patients adhering less than 50% or less of the time in HDT + HWI and less than 50% on DIP Diet were excluded from the study.

## 1. Representation of the Patients who witnessed improvement in passing of Urine as a result of adherence to the GRAD system

Cum.	Percent	Freq.	effect on urine
43.00	43.00	43	more
82.00	39.00	39	same
100.00	18.00	18	reduced
	100.00	100	Total

#### **Corelation tested**

To test if those of followed GRAD fully exhibited greater improvement than among those who followed it partially.

#### Urine

	Urine	
GRAD	Increased	Total
Fully	13 (46%)	28
Partially	30 (42%)	72
Total	43 (43%)	100

The group following GRAD fully have shown higher improvement in urination, however this higher proportion is not found to be statistically significant based on t-test of difference in proportions.

## 2. Representation of the Patients who witnessed improvement in incidence of swelling as a result of adherence to the GRAD system

Effect on swelling	Freq.	Percent	Cum.
never existed	36	36.00	36.00
swelling eliminated	23	23.00	59.00
improved	18	18.00	77.00
same	13	13.00	90.00
deteriorated	10	10.00	100.00
Total	100	100.00	

## **Corelation tested**

## **Swelling**

	Swelling	
GRAD	Reduced/eliminated	Total
Fully	16 (57%)	28
Partially	24 (33%)	72
Total	40 (40%)	100

It can be clearly seen that the subjects who followed GRAD fully exhibited higher improvement in swelling (in terms of both reduction or elimination of swelling). Using the t-test of difference in proportions it is proved that the percentage of subjects who showed improvement in swelling is significantly higher among those who followed GRAD fully as compared to those who followed it partially, with p value of 0.01.

## 3. Representation of the impact on the weakness of patients as a result of adherence to the GRAD system

Effect on weakness	Freq.	Percent	Cum.
reduced increased no weakness ever reported same	47 24 16 13	47.00 24.00 16.00 13.00	47.00 71.00 87.00 100.00

## **Corelation tested**

## Weakness

	Weakness	
GRAD	Reduced	Total
Fully	15 (54%)	28
Partially	32 (44%)	72
Total	47 (47%)	100

The group following GRAD fully have shownhigher improvement in reduction of weakness as compared to those who followed it partially. This higher proportion among the fully GRAD following group is found to be moderately statistically significant at 0.10 level of significance, based on t-test of difference in proportions.

## 4. Representation of the impact on the Breathlessness of patients as a result of adherence to the GRAD system

Effect on			
Breathlessness	Freq.	Percent	Cum.
no breathlessness	47	47.00	47.00
reduced	33	33.00	80.00
increased	16	16.00	96.00
same	4	4.00	100.00
Total	100	100.00	

#### **Corelation tested**

## **Breathlessness**

	Breathlessness	
GRAD	Reduced	Total
Fully	9 (32%)	28
Partially	24 (33%)	72
Total	33 (33%)	100

The group following GRAD fully seems to show lesser improvement in breathlessness than the partial group. However, this difference is not statistically significant. Thus we can conclude there exists no difference in the percentage improvement shown by these two groups.

## 5. Representation of the impact on the dependence on Dialysis of patients as a result of adherence to the GRAD system

Effect on Dialysis	Freq.	Percent	Cum.
reduced	45	45.00	45.00
same	27	27.00	72.00
stopped	25	25.00	97.00
ambiguous	2	2.00	99.00
increased	1	1.00	100.00
Total	100	100.00	

## **Corelation tested**

## **Dialysis**

	Dialysis	
GRAD	Improvement	Total
Fully	21 (75%)	28
Partially	49 (49%)	72
Total	70 (70%)	100

Significantly Higher improvement among the fully following group. The result of t-test of difference in proportions statistically significant at 0.01 level of significance.

## 6. Representation of the impact on the weight of patients as a result of adherence to the GRAD system

effect on

Cum.	Percent	Freq.	weight
69.00	69.00	69	reduced
89.00	20.00	20	increased
100.00	11.00	11	same
	100.00	100	Total

# 7. Representation of the Patients who witnessed improvement in incidence of vomiting as a result of adherence to the GRAD system

effect on vomiting	Freq.	Percent	Cum.
no vomitings	56	56.00	56.00
no longer experienced	21	21.00	77.00
reduced	12	12.00	89.00
increased	7	7.00	96.00
same	4	4.00	100.00
Total	100	100.00	

## **Corelation tested**

## Vomiting

	Vomiting		
GRAD	Reduced	Total	
Fully	11(39%)	28	
Partially	21 (29%)	72	
Total	32 (32%)	100	

Though higher among the fully following group, but the difference is statistically insignificant.

# 8. Representation of the Patients who witnessed improvement in incidence of Itching as a result of adherence to the GRAD system

Effect on Itching	Freq.	Percent	Cum.
no itching	48	48.00	48.00
no longer experiences reduced	12	22.00 12.00	70.00 82.00
same increased	11 7	11.00 7.00	93.00
Total	100	100.00	<del>-</del>

# Corelation tested Itching

	Itching	
GRAD	Improvement	Total
Fully	10 (36%)	28
Partially	14 (19%)	72
Total	34 (34%)	100

Fully following group shows statistically higher improvement in itching. The difference in the percentage of people who showed improvement across fully and partially following group is significant at 0.05 level of significance.

# 9. Representation of the Patients who witnessed improvement in incidence of delirium as a result of adherence to the GRAD system

Effect on Delerium	Freq.	Percent	Cum.
no problem	76	76.00	76.00
increased	7	7.00	83.00
same	7	7.00	90.00
no longer experienced	6	6.00	96.00
reduced	4	4.00	100.00
Total	100	100.00	

## Corelation tested Delirium

	Delerium		
GRAD	Reduced	Total	
Fully	1(4%)	28	
Partially	9 (1%)	72	
Total	10 (10%)	100	

Significantly higher improvement shown among the fully following GRAd group, at 0.01 level of significance.

## 10. Representation of the Patients who witnessed improvement in incidence and frequency of seizures as a result of adherence to the GRAD system

Effect on Seizures	Freq.	Percent	Cum.
no seizures no longer experiencing still continuing deteriorated	92 5 2 1	92.00 5.00 2.00 1.00	92.00 97.00 99.00 100.00
Total	100	100.00	

## Corelation tested Seizures

	Seizures		
GRAD	Reduced	Total	
Fully	2(7%)	28	
Partially	3 (4%)	72	
Total	5 (5%)	100	

Significantly higher improvement at 0.01 level of significance among the fully following group.

#### **Results:**

100 dialysis patients were successfully followed between August 2021 and March 2022 and were grouped as: Group I (who followed GRAD System fully) = 28%

Group II (who followed GRAD System partially) = 72%

53 more patients were disqualified as they either failed to provide data on regular basis or could not qualify ineither group.

## **GROUP -1, Total Patient 28**

Dialysis Status	
Dialysis Free	21
Partially Dialysis Free	7

Dialysis Status				
25%	Dialysis Free			
<b>75</b> %	■ Partially Dialysis Free			

Dependence on Drugs	
Totally Drugs Free	10
Partially Drugs Free	15
No Change In Drugs	3

<b>Drugs Status</b>	
11%	<b>Totally Drugs Free</b>
36%	Partially Drugs Free
53%	No Change In Drugs

Symptomatic Relief ( Vomiting/Breathlessness / Itchin Weakness/ Swelling)	ng/
More than 90% Relief	17
50 to 89% Relief	8
Relief Less than 50%	3
No Relief	0

Symptomatic Relief			
11%		More than 90% Relief	
28%		50 to 89% Relief	
20/0	61%	Relief Less than 50%	

Recommending GRAD SYSTEM to O	thers
I will recommend to others	28
I will not recommend to others	0

	mending Grad em to Others
100%	I will recommend to others

Reduction in Financial Burden	I
Financial Burden Reduced to 70-90%	21
Financial Burden Reduced below	
70%	7

No Reduction in Financial Burden 0	No Reduction in Financial Burden	0
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## **Reduction in Financial Burden Financial Burden** Reduced to 70-90% 25% **75% Financial Burden Reduced below 70%**

CDOID	<b>3</b> .	T-4-1	D-424	72
GROUP	-2:	т отаг	Patient	IZ

Dialysis Status	
Dialysis Free	0
Partially Dialysis Free	72

Dialysis Status	
Dialysis Free	0
Partially Dialysis Free	72
Dependence on Drugs	
Totally Drugs Free	11
Partially Drugs Free	27
No Change In Drugs	34

Drugs S	Status 15%	Totally Drugs Fron
47%		Totally Drugs Free Partially Drugs Free
38%	No Change In Drugs	

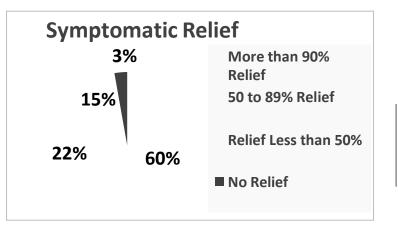
**Partially Dialysis** 

Free

**Dialysis Status** 

100%

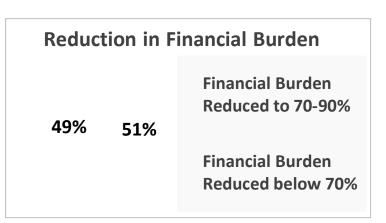
Symptomatic Relief ( Vommiting/Breathlessness / Itch Weakness/ Swelling)	ing/
More than 90% Relief	43
50 to 89% Relief	16
Relief Less than 50%	11
No Relief	2



Recommending GRAD SYSTEM to Others		
I will recommend to others	72	
I will not recommend to others	0	

# Recommending Grad System to Others 100% I will recommend to others

Reduction in Financial Burden	
Financial Burden Reduced to 70-90%	37
Financial Burden Reduced below	
70%	35
No Reduction in Financial Burden	0



Correlation between DIP diet, HDT and HWI with improvement in various symptoms

Corelation Table				
	Following DIP	Following HDT	Following HWI	
Improvement in Swelling	0.2	-0.1	0.2	
Improvement in Urine	0.0	0.1	0.3	
Improvement in Weakness	0.1	0.0	0.3	
Improvement in Vomiting	0.1	-0.2	0.0	
Improvement in Dialysis	0.1	0.2	0.0	
Improvement in Itching	0.0	-0.2	0.3	
Improvement in Breathlessness	0.0	-0.1	0.2	
Improvement in Delerium	-0.1	-0.1	0.2	
Improvement in Seizures	0.1	0.1	0.2	

Positive correlation (though low) of improvement in majority of symptoms, especially in response to DIP diet and HWI. Following HDT exhibits negative correlation with improvement in swelling, vomiting, itching, breathlessness and delirium. Hot water immersion seems to be more highly related to relieving most of the symptoms. For Urine, breathless and vomiting there is no statistically significant difference in improvement of subjects across the fully and partially Grad following group.

Overall Conclusion: It is found that the group following the GRAD fully have shown significantly higher improvement as compared to those who followed it partially for the symptoms of swelling, dialysis, weakness, itching, delirium and seizures. For

## FINANCIAL IMPLICATIONS

## Representation of the Patients who witnessed improvement in their FINANCIAL CONDITIONS as a result of adherence to the GRAD system

Change in Expenditure	Frequency	Percentage
Reduced	56	56
Constant Expenditure	27	27
Increased Expenditure	9	9
Paid by govt/insurance	8	8
Total	100	100

Most of the subjects following the GRAD experienced a marked decrease in their expenditure on treatments, Dialysis and related medications and hospital visits etc.

The total expenditure incurred by the 100 subjects was reduced by enormous amount of rupees 1199200 per month. The average expenditure thus reduced on an average by 23,807 per person over a month for the 56 subjects who experienced a decline in their monthly expenditure.

## If the subjects will recommend the treatment

Will they recommend	Freq.	Percent	Cum.
yes	85	85	85
no response	9	9	94
no	6	6	100
Total	100	100	

There is an overwhelmingly positive response in the patients study group about the keenness to continue the treatment by the GRAD System and also to recommend the treatment to others.

## If the subjects have already recommended the treatment

Have they recommended	Freq.	Percent	Cum.
yes no response no	71 23 6	71.00 23.00 6.00	71.00 94.00 100.00
Total	100	100.00	

#### **Discussion:**

This is a pioneering study aimed at assessing the benefits of GRAD system in reversing CKD among dialysis patients. GRAD system is an unusual amalgamation of the knowledge of human physical engineering in terms of application of gravitational force and hydrostatic pressure on human body and the principles of modern medical science for finding a cure for CKD patients. There is also an Ayurvedic angle to the system which has been derived from the thousands of years of Ayurvedic studies and deep knowledge that is recorded in ancient Indian treatises and which has been verified and found to be accurate and reliable after the employment of modern methods of verification.

**Dr. Biswaroop Roy Chowdhury**, the developer of the GRAD system has an impressive, wide ranging and comprehensive academic background which has enabled him to draw upon various disciplines, sciences and subjects to offer a potent combination of therapies and treatments for CKD reversal, among other pioneering breakthroughs in medical practice and theory.

In addition to being an engineering graduate and post-graduate specializing in Diabetes, he has also successfully acquired a PhD in Diabetes care. The rich diversity and innate depth in his education has helped him in combining **Physics** of the surroundings with **Chemistry** of the human body and **Biology** of the innate bodily ecosystem in human beings to reactivate, energise and resuscitate even a dying kidney. As evident from the data, CKD patients could successfully lowerthe burden of the disease partially/fully. Surely, GRAD system is having the potential to revolutionize the way lifestyle illnesses are treated.

GRAD system can be followed safely and with minimum resources in the privacy, security and convenience of the patient's home even in rural areas, without requiring elaborate equipments or expensive medications.

It is also seen only 28% of the patients could follow the GRAD System fully and hence, majority of the patients could not get the expected full benefit of the GRAD System. Therefore, there is a pressing need to create a GRAD System friendly environment, reliable medical ecosystem and viable infrastructure around the patients so as to make the process of following the HWI/HDT and D.I.P Diet convinienet and enjoyable. The innovative mind of the patients and their strong belief in the GRAD System is evidenced by their inventive home-based GRAD Dialysis tub. This aspect is very encouraging and relevant in regard to the wide spread and dissemination of the GRAD system and in increasing its application and effectiveness across the globe. A few of the innovative ideas are captured in the following pictures:

# **INNOVATION BY PATIENTS**













# **INNOVATION BY PATIENTS**





**HWI with Industrial Plastic Container** 



**HWI with Cemented Tub** 



HWI with online available Home Inflatable Bathtub

90% of the patients reported a great amount of resistance and non-cooperation from their dialysis centers when the patients were in the process of reducing the frequency of dialysis in response to the improvement in their symptoms. This unfortunate, but understandable resistance from the dialysis centers (as they were losing a great deal of financial gain and patients) was a major factor why over  $1/3^{\rm rd}$  of the patients discontinued the GRAD System midway. To address this issue, training, awareness and orientation programs for the medical and support staff, caretakers, patients and technicians must be regularly undertaken to teach the proper application and resultant benefit of the GRAD system all across the country.

## **CONCLUSION:**

GRAD system can be recommended as an effective method to reverse CKD among mild, moderate and severe CKD patients and can be seen as an effective alternative to dialysis and kidney transplant.

Further, the GRAD system has shown positive results in reversing various comorbid conditions including Diabetes and heart diseases and can be recommended for the benefit of the patients suffering from these conditions. It must be noted that no side effects or adverse events were reported during the entire study.

## Scope of further research

- ✓ Impact of hot tubs on prevalence of kidney disease in western nations where hot tubs are a part of the daily bathing rituals.... comparative analysis with nations like India where bath tubs are not in use. Has the unconscious incorporation of the hot tub treatment helped the European nations where bath tubs are frequently in use to bring down the risk of CKD.
- ✓ Currently, the therapy being used does not include the addition of oils, vata, pitta and grita substances as recommended in the actual Avagaha Sweda process. Further research can be conducted upon the addition of various substances to the HWI and the subsequent impact on the success of the GRAD systems.
- ✓ It is further suggested that Asvagh Sweda can be incorporated into modern spa culture and this would add to the efficacy of various spa treatments and boost their health giving properties and medicinal value. This treatment can prove to be highly relaxing and thereupatic for the body.

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29.

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Signature	Signature
Stamp	Stamp

## ANNEXURE 1

## **Questionnaire for patients**

	Daily Diet and Mo	edication Form (HIIMS)	
Date:			
Name:		Email:	
Mobile:	Profession:	Gender:	DOB
Address:			
Weight:Height:			
Language in which you wan	t a diet plan: Hindi:	, English:	

Do you smoke:Do you consume alcohol:
Allergies(Food):
Vegetarian:non-Vegetarian:
Present Status of your teeth/ Can you chew raw food comfortably:
Medical condition(s)/Disease(s): -
Name of the Medications taken along with dosage: (CAPITAL LETTERS)
Duration: For how long have you been taking this/these medicine(s)
Do have any Discomfort/symptoms/ Unusual Feeling presently? (MANDATORY TO ANSWER. Please write 'NODISCOMFORT' in-case you do not have any discomfort or symptoms.
Do you have any Pain? If yes, please name the area which is paining and intensity of pain on a scale of 1-10.
Your Daily Diet:
Early morning, the first thing you eat/drink:
Breakfast:
10am - 12noon: Mid-morning Snacks :
Lunch: 4pm - 7pm: Evening Snacks :

Late night snack:	

Physical Activity:	
Morning:	Afternoon:
Evening and Night:	
Sunshine;	
Iaut (Explained to me in Welcome N	chorize HIIMS and its medical team to Treat me as per their treatment plan