Department of Engineering
School of Engineering & IT
ARKA JAIN UNIVERSITY, Jamshedpur

Report on Granted Australian Innovation Patent

Mandatory format for all Academic – Non-Academic Event

1	Type of the Event	Academic
2	Name of the Event	Australian Innovation Patent
3	Date of the Event	**26 October 2021**
4	Details of the Event	**The Commissioner of Patents, Govt. of Australia has granted the patent on Machine Learning Based Diagnosis Of Chronic Kidney Disease In Diabetes Patients and certifies that the particulars have been registered in the Register of Patents. The Patent Terms Eight years from 25 August 2021**
5	Event Author and Inventor	Dr Binod Kumar Choudhary, **Assistant Professor of Physics** **Department of Engineering** **School of Engineering & IT**
6	Event Coordinators (Faculty)	N.A
7	Event Coordinators (Student)	N.A.
8	Budget Sheet for the Event	N.A.
9	Attach Photograph	Yes (Poster)
10	Attach press release (if any)	N.A.
11	Result of the Event (if event is result based)	N.A.
12	Copies of MOM	Yes

Title of the Invention

MACHINE LEARNING BASED DIAGNOSIS OF CHRONIC KIDNEY DISEASE IN DIABETES PATIENTS

Name and address of patentee(s):

1. Dr.Pokkunuri Pardha Saradhi, Professor, Department of Electronic and Communication Engineering, Koneru Lakshmaiah Education Foundation, Officially KL Deemed to be University, Vijayawada, Andhra Pradesh, India
2. Dr.Raghava Yathiraju, C/o St. Marys Group of Institutions Guntur, Guntur-Bapatla Highway, Chebrolu (V&M), Guntur District, Andhra Pradesh, India
3. Sreedevi S, Chitkara University Institute of Engineering and Technology, Chitkara University, Chandigarh-Patiala National Highway, Punjab, India
4. Dr. Usha Bhanu.N, Professor, Department of ECE, SRM Valliammai Engineering College, SRM Nagar, Kattankulathur, India Chitransh dixit, BE in computer science and engineering, RV Institute of Technology and Management, Bangalore India
5. Pankaj Sahu, Research Scholar, Dept.of ECE, SoET, BML Munjal University, 67th KM. Milestone, National Highway 8, Near Kapriwas, Gurugram, Haryana, India
6. Rakesh Patel, Assistant Professor, OIST Jabalpur, OIST Jabalpur, oriental campus, Andhua, Bhedaghat By-pass Road, Jabalpur, M.P., India
7. Dr Binod Kumar Choudhary, Assistant Professor, Department of Physics, ARKA JAIN University, Jamshedpur, Jharkhand, India
8. Dr Anil Maheshwari, Assistant Professor, Department of Mathematics, Engineering College Ajmer, India
9. Dr. Durgacharan Arun Bhagwat, Assistant Professor, Department of Pharmaceutics, Bharati Vidyapeeth College of Pharmacy, Kolhapur, Maharashtra, India
10. Saravanakumar C, Assistant Professor , Department of ECE, SRM Valliammai Engineering College, SRM Nagar, Kattankulathur India
11. Dr. S. Pothalaiah, Professor,Department of Electronics and Communication Engineering, Vingana Bharathi Institute of Technology, Hyderabad, Telegana, India

Name of inventor(s):

Saradhi, Pokkunuri Pardha ; Yathiraju, Raghava ; S, Sreedevi ; N, Usha Bhanu ; dixit, Chitransh ; Sahu, Pankaj ; Patel, Rakesh **; Choudhary, Binod Kumar** ; Maheshwari, Anil ; Bhagwat, Durgacharan Arun ; C, Saravanakumar ; Pothalaiah, S.

Term of Patent:
Eight years from 25 August 2021

About the Research Patent:-

1. FIELD AND BACKGROUND OF THE INVENTION

Chronic kidney disease (CKD) is a complex pathophysiological process resulting from multiple etiologies. CKD is a major cause of morbidity and mortality worldwide and frequently leads to end-stage renal disease (ESRD), which is irreversible and renders the patients permanently dependent on renal replacement therapy. Therefore, it is considered a significant public health problem that places huge burden on global healthcare resources.

Despite ongoing investigations of the pathogenesis of CKD, much remains unexplained. CKD results from varied etiologies, diabetes being a frontrunner amongst them. Prolonged hyperglycemia in diabetic patients is the major cause of all micro and macro-vascular complications including diabetic nephropathy which may develop at a later stage of the disease. Clinical studies such as Diabetes Control and Complications Trial (DCCT) and UK Prospective Diabetes Study (UKPDS) have shown that intensive glycemic control retards the progression and development of microalbuminuria and overt nephropathy. Hyperglycemia leads to increased availability of glycolytic intermediates causing their diversion into other pathways such as the polyol pathway, hexosamine pathway, protein kinase C (PKC) pathway and the advanced glycation end (AGE) products pathway which are ultimately linked to the manifestations of diabetic micro- and macro-vascular complications.

2. BRIEF DESCRIPTION OF THE SYSTEM

CKD may result from multiple etiologies like diabetes (41%), hypertension (22%), chronic glomerular nephritis (16%) etc. DM has emerged as the single most important cause of CKD. Diabetic nephropathy has been considered a non-immune disease; however, recent evidence shows an increase in macrophage infiltration and overproduction of leukocyte adhesion molecules in kidneys from diabetic humans. There is growing support for the notion that inflammation plays a key role in the pathogenesis of diabetic nephropathy. Leukocytes, monocytes, and macrophages have all been implicated in the process. Reactive oxygen species are continuously generated in physiological conditions and effectively eliminated by several intracellular and extracellular antioxidantsystems. Oxidative stress and resultant tissue damage are hallmarks of chronic disease and cell death; diabetes is no exception. A causal relationship between chronic hyperglycemia and diabetic micro-vascular disease, long inferred from various animal and clinical studies. The mechanisms by which hyperglycemia causes tissue damage and resultant clinical complications, can be conceptually divided into two categories: One is rapid change in intracellular metabolites in response to hyperglycemia, such as activation of diacylglycerol-protein kinase C (DAG-PKC) pathway enhanced polyol pathway, and arachidonic acid metabolism the other is slow change in intracellular and extracellular proteins owing to

hyperglycemia induced covalent modification. Tumor necrosis factor-alpha, a proinflammatory cytokine plays an important role in the pathogenesis of many chronic inflammatory, autoimmune and infectious diseases. DNA sequence variation (polymorphism) in the promoter regions of gene encoding TNF-α may alter its expression level and thus affect

the outcome of the disease. Therefore, attention has been focused on TNF promoter region and eight DNA variants or 'SNPs' have been described within promoter region of TNFA gene. Mainly eight SNPs of TNFA gene have been reported in humans. Out of these multiple SNPs, - 308G→A (s1800629) variant has been frequently studied in Type 2 DM in different populations and has also been found to be significantly associated with diabetic nephropathy in North Indians and is a strong predisposing risk factor for CKD.

a. Obtaining a test sample from suspected subject;
b. Estimating genetic polymorphism in Tumour Necrosis Factor-Alpha gene (TNFA)- parameter 1 in the sample obtained;
c. estimating oxidative stress levels -parameter 2 in the sample obtained
d. estimating levels of pro-inflammatory markers- parameter 3 in the obtained sample; and
e. comparing the values of parameter 1 with 2 and 3 obtained with the control samples.

Novel SNPs like -863C→A (rs1800630) and -1031T→C (rs1799964) have also been associated with few chronic inflammatory diseases, autoimmune diseases and cancers. Since Type 2 diabetes mellitus is associated with high oxidative stress and chronic inflammation, therefore the above-mentioned SNPs might play an important role in the pathogenesis and severity of diabetic nephropathy.

The present invention has therefore combined these three parameters to develop a method for estimating chronic kidney disease predisposition in diabetic patients.

In one embodiment the present invention discloses a method of estimating chronic kidney disease predisposition in diabetic patients comprising;

The study groups may be broadly categorized in groups- Control -Group I: Healthy controls (HC), Test group mainly constituting three further groups that are Group II, III and IV. Group II: Patients with Type 2 diabetes mellitus without nephropathy (DM), Group III: Patients with Type 2 diabetes mellitus with nephropathy (DM-CKD). In one embodiment, the samples from all the groups may be obtained. The sample may be serum, whole blood and plasma depending upon the biochemical assay that needs to be carried out.

In another embodiment, the genetic polymorphism in TNF-A may be elucidated by single nucleotide polymorphism at gene position of -1031T→C and -863C→A in TNF-A gene. In another embodiment, the genetic polymorphism in TNF-A gene may be estimated by polymerase chain reaction (PCR) and Restriction fragment length polymorphism (RFLP) technique. Analysis of the prevalence of different genotypes of -863C→A in present invention show that C/C genotype was most prevalent (60%) followed by C/A (35.5%) and A/A genotype (4.5%). Genotypic analysis of the prevalence of different genotypes of -1031T→C showed that T/T genotype was most prevalent (78%) followed by T/C (21%) and C/C genotype (1.0%). In another embodiment the estimation of oxidative stress level comprises estimation of reduced Glutathione (GSH) in test samples; malondialdehyde (MDA) in test samples;and reducing Ability of Plasma (FRAP) estimation in the test sample

obtained. The Glutathione content in blood was measured using dithio-nitrobenzene (DTNB). Glutathione-S-transferase activity in plasma was measured spectrophotometrically using 1-chloro-2,4-dinitrobenzene (CDNB) as substrate, MDA was determined by measuring the thiobarbituric acid reactive substances (TBARS) in plasma. The antioxidant capacity of blood was determined by measuring the ability of plasma to reduce Fe+3 to Fe+2. Fecl3 (20 mM) reacted with 2,4,6 trispyridyl-s-triazine (TPTZ) to form ferric-

tripyridyltriazine (Fe+3-TPTZ) complex. In one embodiment estimation of pro-inflammatory marker level comprises levels of TNF-alpha in test samples; and levels of hsCRP (Plasma High-sensitivity C- reactive protein) in test samples. The invention is herein described, with the accompanying block diagrams. Wherein: Figure 1. Overall Architecture of Machine Learning Based Diagnosis Of Chronic Kidney Disease In Diabetes Patients

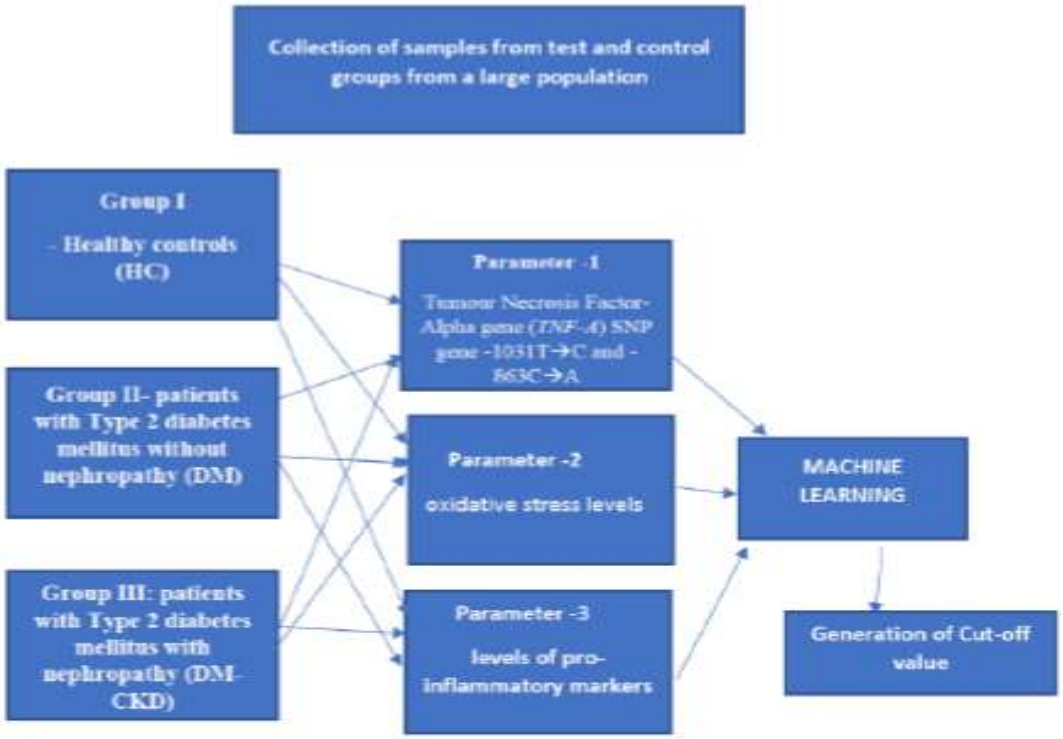

Figure 1. Overall Architecture of Machine Learning Based Diagnosis Of Chronic Kidney Disease In Diabetes Patients

CLAIMS

We Claim:

1. A method of estimating chronic kidney disease predisposition in diabetic patients comprising;
   a. obtaining a test sample from suspected subject;
   b. estimating genetic polymorphism in Tumour Necrosis Factor-Alpha gene(TNF-A)-parameter 1 in the sample obtained;
   c. estimating oxidative stress levels -parameter 2 in the sample obtained

d. estimating levels of pro-inflammatory markers- parameter 3 in the obtained sample; and
e. comparing the values of parameter 1 with 2 and 3 obtained with the control samples.2

2. The method of estimating chronic kidney disease predisposition in diabetic patients as claimed in claim 1, wherein the sample can be serum, whole blood and plasma.
3. The method of estimating chronic kidney disease predisposition in diabetic patients as claimed in claim 1, wherein cut-off value for predisposition to chronic kidney disease is calculated by a pre-trained machine learning using the values of parameter 1, 2, and 3 of test samples and control samples.
4. The method of estimating chronic kidney disease predisposition in diabetic patients as claimed in claim 1, wherein the control sample is obtained from group I - healthy controls (HC), test sample is obtained from group II- patients with Type 2 diabetes mellitus without nephropathy (DM), group III: patients with Type 2 diabetes mellitus with nephropathy (DM-CKD).
5. The method of estimating chronic kidney disease predisposition in diabetic patients as claimed in claim 1, wherein pre-trained machine learning using the values of parameter 1, 2, and 3 of test samples and control samples is carried out by K- means Clustering Algorithm.

ABSTRACT

Chronic kidney disease (CKD) is a complex pathophysiological process resultingfrom multiple etiologies. CKD is a major cause of morbidity and mortality worldwide and frequently leads to end-stage renal disease (ESRD), which is irreversible and renders the patients permanently dependent on renal replacement therapy. Therefore, it is considered a significant public health problem that places huge burden on global healthcare resources. A method of estimating chronic kidney disease predisposition in diabetic patients based on Machine learning algorithm that involves; obtaining a test sample from suspected subject; estimating genetic polymorphism in tumour necrosis factor alpha gene (TNFA gene) - parameter 1 in the sample obtained; estimating oxidative stress levels -parameter 2 in the sample obtained; and comparing the values of parameter 1and 2 obtained with the control samples.

Patent Poster

Australian Innovation Patent system is designed by the government to protect an incremental advance on existing technology rather than being a ground-breaking invention.

An innovation patent is only legally enforceable if it has been examined by IP Australia and found to meet the requirements of the Patents Act 1990, and has been certified.

Our Assistant Professor Dr. Binod Kumar Choudhary had been granted by innovation patent Australia for his research on "MACHINE LEARNING BASED DIAGNOSIS OF CHRONIC KIDNEY DISEASE IN DIABETIC PATIENTS."
Congratulations Sir for your Achievement. ✨✨
#achievements #innovationforfuture #success #proudmoment #ajudairies #arkajainuniversity

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nd address of patentee(s):

uri Pardha Saradhi, Professor, Department of Electronic and Communication Engineering, Kc iah Education Foundation, Officially KL Deemed to be University, Vijayawada, Andhra Pradesh

ava Yathiraju, C/o St. Marys Group of Institutions Guntur, Guntur-Bapatla Highway, Chebrolu (V District, Andhra Pradesh, India

i S, Chitkara University Institute of Engineering and Technology, Chitkara University, Chandigar Highway, Punjab, India

a Bhanu.N, Professor, Department of ECE, SRM Valliammai Engineering College, SF ilathur, India

h dixit, BE in computer science and engineering, RV Institute of Technology and Managemer re India

Sahu, Research Scholar, Dept.of ECE, SoET, BML Munjal University, 67th KM. Mileston Highway 8, Near Kapriwas, Gurugram, Haryana, India

Patel, Assistant Professor, OIST Jabalpur, OIST Jabalpur, oriental campus, Andhua, Bhedagh Road, Jabalpur, M.P., India

d Kumar Choudhary, Assistant Professor, Department of Physics, ARKA JAIN Universit dpur, Jharkhand, India

Maheshwari, Assistant Professor, Department of Mathematics, Engineering College Ajmer, India

acharan Arun Bhagwat, Assistant Professor, Department of Pharmaceutics, Bharati Vidyapee of Pharmacy, Kolhapur, Maharashtra, India

akumar C, Assistant Professor , Department of ECE, SRM Valliammai Engineering Colleg gar, Kattankulathur India

Pothalaiah, Professor,Department of Electronics and Communication Engineering, Vingar Institute of Technology, Hyderabad, Telegana, India

nvention:
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f inventor(s):

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Patent:

Eight years from 25 August 2021

Dated this 26th day of October 2

Commissioner of Patents

PATENTS ACT 1990

Patent Certificate:-

Australian Government
IP Australia

CERTIFICATE OF GRANT
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Patent number: 2021107110

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Name and address of patentee(s):

Dr.Pokkunuri Pardha Saradhi, Professor, Department of Electronic and Communication Engineering, Koneru Lakshmaiah Education Foundation, Officially KL Deemed to be University, Vijayawada, Andhra Pradesh, India

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Dr Binod Kumar Choudhary, Assistant Professor, Department of Physics, ARKA JAIN University, Jamshedpur, Jharkhand, India

Dr Anil Maheshwari, Assistant Professor, Department of Mathematics, Engineering College Ajmer, India

Dr. Durgacharan Arun Bhagwat, Assistant Professor, Department of Pharmaceutics, Bharati Vidyapeeth College of Pharmacy, Kolhapur, Maharashtra, India

Saravanakumar C, Assistant Professor , Department of ECE, SRM Valliammai Engineering College, SRM Nagar, Kattankulathur India

Dr. S. Pothalaiah, Professor,Department of Electronics and Communication Engineering, Vingana Bharathi Institute of Technology, Hyderabad, Telegana, India

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Term of Patent:

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COMMONWEALTH OF AUSTRALIA AUSTRALIA PATENT OFFICE

Dated this 26th day of October 2021

Commissioner of Patents

PATENTS ACT 1990

The Australian Patents Register is the official record and should be referred to for the full details pertaining to this IP Right.

Signature

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Signature Event Lead	Signature Event Lead	Signature Event Co-ordinator Faculties	Signature Event Co-ordinator Faculties	Signature Event Co-Ordinators student