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RESEARCH ARTICLE

SERENDIPITY OBSERVATIONS ON PICORNA VIRUS: PROMISE OF A CURE FOR INFLUENZA AND CORONA UNDER THE SEVENTEENTH LAW OF THE UNIVERSE

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ABSTRACT

Serendipity is known as the way great researches are done. The present methodology involves *Solanum xanthocarpum* used in natural form to act potentially antiviral. The said biological herb is rich in glycoalkaloids like solasodine, solasonine and solamigrine etc. The active ingredients are present throughout all parts of plant but for convenience sake, accuracy and efficacy, only ripe and near ripe berries are used which are then dried as per the pharmacognosial recommendations, powdered and packed airtight away from moisture, heat or direct sunlight. The antiviral preparation is administered by oral route and used in case to counter the infection caused by picorna virus of genus *Aphthovirus*, species *FMD virus* from family *picornaviridae*. The same preparation has also been found to be effective against other virus species like influenza and a disease with corona like symptoms by same methodology however in limited cases. Results are drawn on simple percentage basis calculation and analyzed. The drug formula is very safe. No noticeable small, big or special side effects were seen in any of the administrations. Therapeutic correlation is recommended in the use of this broad spectrum powerful antiviral dosage regimen. The study on individual active phytochemicals is recommended in future explorations, however rendered much easier with the striking performance outcome of this drug in the present example and is sure to pave way for milestone breakthroughs in the fight of humanity against viral infections of present and future.

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INTRODUCTION

The seventeenth law of the universe is defined as the force that describes that the universe tends to bend in a direction to bestow upon mankind the gift of great scientific discoveries (Wikipedia). The other name for this is serendipity. Almost all big discoveries or a big chunk of them that transformed the world so radically, belong to this category. This is another question that nature selects super scientific geniuses, then trains and equips them suitably to stand candidates to report such exploits. A mega discovery is usually not planned but happens in the form of a flash idea in the mind of a scientist that is associated with a happening taking place in front of him and he is able to understand the principle or importance of it in transforming the existing knowledge about science. Such persons are worthily been known as solitary inventors. The same truth is applicable in the field of medical research. The great discovery of penicillin by Alexander Fleming is a most conspicuous example of this. "...penicillin started as a chance observation.

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My only merit is that I did not neglect the observation and that I pursued the subject as a bacteriologist" (Fleming, 1945). In 1889, Oscar Minkowski and Joseph von Mering while studying the effects on digestion removed a dog's pancreas and surprisingly found flies feeding off the dog's urine. This sudden observation later paved way for the discovery of insulin by John Banting and others. A surprise and somewhat weird looking idea in the brain of Louis Pasteur that the microorganism responsible for rabies might be sitting in the brain of the animal rather than being in the blood because the brain urges it to bite, served the foundation for the development of rabies' vaccine. Even the great work done in the field of cryo-preservation by Polge & Smith was a case of serendipity (Hunter, 1982). The present discovery is also an act belonging to this category. The universe and its laws are certainly above the reach and scope of man, governments and legislations and the great & almighty Mother Nature has displayed the credibility of this criterion on countless occasions. We all are very much familiar with the power and might of it. Devastating rains and hurricanes do come. Earthquakes do happen and tsunamis ransack nations. Epidemics and pandemics also occur in various parts of the world. All these are the display of the supremacy of nature.

Viral infections are a big challenge for mankind as of today. The drugs as worthy as antibiotics and sulphonamides; used effectively against bacterial infections, are simply not working against virus and vaccines are not easy to develop especially in case of fast mutating RNA viruses. So, a chemotherapy breakthrough is the only option left and fortunately the discovery of the antiviral properties of *Solanum xanthocarpum* as described and disclosed in the patent application in Indian patent office (Aulakh & Dhull, 2011) has just knocked on the doorstep of humanity and it becomes the supreme duty and responsibility of us all including the governments, organizations and the supra governmental bodies like world health organization (WHO) and united nations (UN) to welcome it and not sabotage this golden opportunity against viral infections of today and of course for the future to come.

MATERIALS AND METHODS

The present study was undertaken by the Department of Applied Pharmacology of the Gregor Mendel Institute for Research in Genetics, Ludhiana under the guidance of B.S. Aulakh, the director of this institute and also the co-discoverer of this drug formula in the form of field trials of serendipity nature in the plains of Punjab and Haryana states of India. The materials and methods include the natural ingredients of *Solanum xanthocarpum* from family Solanaceae. The active constituents are contained in all parts of the plant but for accuracy and efficiency, the ripe or near ripe berries of the plant are collected, separated from the spiny accessories, washed, dried and then powdered under strict pharmacognosial specifications regarding procurements of crude drugs. The semi fine powder is then packed in gelatine capsules of 500 mg each by manual or machine operation without additives like coloring or flavoring agents and preservatives. In an altered embodiment, the pharmaceutically compatible preservatives can also be added after careful investigation. The finished capsules are then stored as per specifications in a cool dry place in normal temperature range away from direct sunlight or heat. The dose is then used on animals or volunteers as the case may be by oral administration. The results are then noted as observed during the progress of the treatment and analyzed.

OBSERVATIONS

Since this discovery is the result of sudden and instantaneous forces of serendipity, the first results were noted on cattle and buffaloes during an FMD (foot and mouth disease) outbreak as late as year 2000. FMD is a picorna virus disease. Since there is no treatment for the disease and only a vaccine is available; so the outbreak leaves the animals not vaccinated (and also not vaccine protected) and exposed to infection with not a choice except to suffer the agony of the disease. The misery of such animals is well known to farmers and veterinarians in the field. This was perhaps the way this sudden discovery took place and got tried on number of animals across a very long period in parts during many outbreaks in Haryana and Punjab states. The actual number however runs into hundreds but we have enumerated the data on 53 such animals; cows and buffaloes, as given in the Table 1 below. The outcome was a very sharp and fast recovery from the disease. The progress of appearance of ulcer development, open wounds, blisters on hoofs and mouth and lips were just stopped on the second day after administration of medication.

The fever subsided during a mere two days treatment of 2000 mg daily dose as a single dose and the animals hastened on a path to recovery. The results are conspicuously visible on the second day of treatment itself. However the usual administration of antibiotics, antiseptics etc continued for the wounds and secondary infections that had already been incurred during the passage of disease. For influenza also the sudden and by chance administration on 16 subjects of the 500 mg dose two times a day for three days resulted in very fast recovery in the shape of decrease in fever, coughing frequency, body aches, burning throat and heavy chest and running nose and for another disease resembling characteristics of novel corona (however in the absence of proper testing protocols, it can not be ascertained with accuracy that this disease is surely corona or some distant or close relative of it or some other disease just resembling it characteristics wise) without severe pulmonary pneumonia features but surely with very strong persistent dry cough with respiratory obstruction & difficulty for many days (even weeks), mild fever, shortness of breath, tiredness, nausea, body pains, pain in the abdomen, loss of smell and taste; the results were visibly very good with 500 mg two times a day dose for seven such subjects after four days of treatment.

RESULTS AND DISCUSSION

Although a surprise discovery, but even then the results are very sharp and conspicuous to be noted in case of the picorna virus on cattle and buffaloes. The farmers however panicked by the sudden struck of their animals preferred to go for the treatment of their animals and they took the medicine on their own individual initiative and responsibility and the result was that the drug performed as outstanding and the recovery was a very fast track one. The same was the case of the drug gotten tested on influenza and the disease with corona like symptoms. There is a point to be noted that a disease resembling corona had definitely spread in north western parts of India well in and before the autumn of 2018. To know exactly that it really existed then or prior to that or not in these or other parts of the country, a well planned and careful clinical audit of at least ten big hospitals of India with largest OPD input regarding occasional and seasonal infections like malaria, dengue, typhoid, viral fever etc should be undertaken for at least five or if possible up to ten years or so from the present day. For a pandemic of the nature and size of corona, it will not be a big endeavor in any way.

A lot of valuable information can be drawn from such an exercise. The subjects recovered and the relief was visibly felt by the subjects as noticeable in the present exercise. Such trials as enumerated above may be called preclinical trials or what or even some more predecessor of them or even they may be called 'strictly serendipity trials' because for a trial to be counted a clinical trial; lot of formalities, procedure work and protocols have to be followed. Heavy finances, organizational interventions and infrastructure etc are needed. Such things being strictly beyond the reach of a solitary drug inventor or small organizations, we leave it on further explorers to work on this medication and report what their individual experiences on the performance of this natural drug formula are? Even someone may try on phytochemicals involved. The preferred ones are solasodine, solasonine and solamigrine etc. We will always be there to extend our help and cooperation whenever or howsoever it is asked to be provided.

Table 1. Showing the effect of drug on picorna (fmd) infected animals

Sr. No.	No. of animals treated	Fever condition	Open wounds, blisters etc.	Side effects	Special adverse effects	Mortality	Recovery
1.	53	Subsided, turned to normal by the second or third day after treatment	Progress of wounds, blisters stopped on second day, then healed to normal	Not seen in any of the cases, no abnormal behavior of animals seen	Not seen in any of the cases	Nil	All animals i.e. 53 healed to normal on completion of treatment

This promising broad spectrum antiviral discovery should not be let to die a silent death and surely the purpose of this write up is to bring it in the notice of scientific community worldwide to further investigate from a point, we are leaving. We have collected data at least which lands this project well beyond the domain of phase two clinical trial. The dosage regimen is calibrated. The side effects are studied and nullified. The efficacy is established. We are now definitely in the phase three, result and outcome wise. If on a fine day some big pharmaceutical company or some government or some other organization wishes us to be a party of such future trials and solicits cooperation from us; we will certainly be more than obliged to be part of such a scientific dream venture. The way this research is reported, may look queer to many but there are certainly some points to be discussed to understand why this track of reporting drug discovery of gigantic proportions is followed as discussed in paragraphs given below.

The seventeenth law of the universe: Serendipity, also called the seventeenth law of universe is the force which decides most of the big inventions to happen on this earth. It is a different question that nature produces persons with super genius to do such conquests. We remember them as great discoverers and the whole world stands in memory and respect to such heroes of history but there are also the forces of darkness that also do prevail on this planet. Such forces as represented by the ones guided only by their vile and selfish interests of begetting more and more wealth and in the bargain thrust countless misery and suffering on the poor mankind.

It is not a secret that big multinational drug corporations have lot of money and resources with them. It is also no secret that they are known for their insatiated greed for profits and due to their power and influence, can manipulate and impress any government in the world. By the same process, they can also impress and manipulate international organizations like WHO and get it to perform in tandem to their tunes. It is in fact such a collective force of them which leads various governments to suitably amend or make new legislations that result in commercial benefits for these organizations. Even international consensus and opinion in media, civil society and intelligentsia is created as such by unleashing most magnificent and wonderful propaganda and publicity. The nature of the world is such that it is home to many problems. The diseases which are still incurable and the newer ones like unknown virus epidemics that are reported across the globe almost routinely every few years; are a big nuisance for the mankind. But these problems are God sent opportunities for these profit hungry big companies. They have a scope for making further wealth if such problems continue to exist but if some super genius known as solitary drug inventor sitting somewhere in a remote and unknown corner on the earth comes up with the drug treatment for such an epidemic, then

the chances of minting countless money by these organizations will simply not mature. So this should be stopped for the monetary benefits of these organizations. And this is exactly what has happened but by a mechanism that no one on earth can easily understand as to how it has come to operate. Very good terms have been coined like 'good clinical practice (GCP)', 'good laboratory practice (GLP)', 'good manufacturing practice (GMP)' etc. These things have come to stand now a days even over and above the very professions, they stand to represent and there is only one agency worldwide that is behind all this known as WHO which is the international health wing of UN. Now who controls WHO? By established norms it appears that various governments across the globe have a hand in controlling it but in practice, it is just the opposite. It is WHO these days that influences various governments and they gladly seem to accept the guidance and control of it in their healthcare systems and even in their legislations and strangely enough these legislations are oriented in one and only one direction of the generation of more and more of profits for these multinational drug houses. In this process, at first the concept of GMP was introduced in various countries and immediately the small and medium sector in drug manufacturing just disappeared or it was cornered to work in a restricted form. GMP in fact is nothing but unconditional forceful surrender of small and medium size industry to either act with super high capitalization oriented work mode of the gigantic drug corporations and invest heavily on additional unwanted infrastructure accessories or just be out of the race. The result was the monopoly of big drug corporations in drug manufacture. The prices of ordinary and life saving drugs went up as a result. This process has succeeded in majority of rich and third world countries. The next step was to introduce this process into clinical practice under the name of GCP and the corporatization of hospitals materialized and medical treatments became super expensive. We all know of this in India. Similarly the concept of GLP made laboratory procedures exorbitantly highly priced and out of the reach of poor and vulnerable patients. The point to be noted here is the use of the word 'Good'. Actually it should have come to stand 'God damn'.

After resorting to all this and making the entire system of healthcare out of the reach of poor and middle class citizens of even the rich and developed countries, we need not to mention the plight of poor and middle class in poor third world countries; the WHO went one step forward. It introduced these terms even in the arena of drugs research. And drugs research jumped out of the reach of poor, isolated solitary drug inventors. It became so expensive. The point to be noted here is that these are the solitary drug inventors who have pioneered almost all big drug discoveries for major diseases including the discovery of penicillin and insulin etc. The drug research now became a super expensive total corporate affair under new laws.

The average cost of a single drug from discovery to market is calculated at exorbitant U.S. \$ 2.6 billions as calculated by Tuft's Centre for Study of Drug Development (Policy and Medicine). The point to be noted here is that it is for a drug molecule developed and not for a treatment discovered. It is again a farce that not a single worthwhile drug discovery able to cure an incurable disease of conventional or viral nature has happened in the last fifty or seventy years or so. This cannot be considered an achievement by any standards and the whole credit for this goes definitely to WHO which has cornered and thrown solitary drug inventors out from the field of drug discovery by such a process. Very petty drugs like pain killers, anti-diabetics, new antibiotics, blood pressure regulators, cholesterol fighters, color & beauty enhancers etc are reported as a routine which are known in drug discovery circles as "me too drugs". They are big money churners and much easier to develop when compared to find treatments for killer incurable and viral diseases. And drug corporates are no charitable organizations either. They are business houses. They will cater only to their most pious interests of making as much money as they can even with the tool of doing or pretending to be doing drugs research. This is in fact the thing they have been doing since the last fifty or seventy years. The real drug inventor i.e. solitary drug inventor is out of the race and the pseudo protocol procedural drug inventors with these super rich corporations and also the ones sitting in government run institutes and universities, usually heavily financed & sponsored by drug companies and working in tune with this new system; are trying to imitate the process of drugs research. The nature opts to select the super talented solitary drug inventors for this purpose but the WHO wants it on the otherwise. The other agencies like federal food and drugs agency (FDA), medical research councils in various countries etc are other allies in the game or they have been so tamed with due course of time along with the drug control regulatory that have been so directed with new rules and legal enactments. It is also true that each country in the world has its own drug regulator which is legally bound to act in tune with new provisions benefiting none other than the powerful drug houses.

Safety & adverse effects: The drug formula did not display any side effects in any of the administrations. No special adverse effects were noted. However it should be added that alkaloid solasodine in the present formula may prove teratogenic in very high quantity (Wikipedia) but in the present case, the dose under study is thousands of times lesser to such a high dosage level. Wikipedia describes this high dose at 1200-1600 mg/kg of body weight for solasodine. Moreover 500 mg of pure dried herb may contain only 12-20 mg of solasodine in the present exercise that comes out to be nearly 0.2-0.3 mg/kg body weight for humans and about 0.1-0.15 mg/kg body weight for animals. In a study on this formula undertaken in Uttar Pradesh, India (Gangawar et al, 2013), no evident signs of toxicity were seen in albino rats at doses even as higher as 1000 and 4000 mg/kg body weight. Even no mortality was observed. In another study in Gujarat, India (Patel et al, 2010), also on albino rats with dosage of 300 mg/kg of body weight given orally, no adverse effects were seen with isolated compounds of berries during 24 hours observation period after administration. No mortality was observed either. The present dosage is however very minuscule when compared to these dosage regimens.

New diseases and pandemics: It is true that new diseases do occur and they have become more a matter of routine happening in the world of today. We know of them and the list is very long namely AIDS, hepatitis, bird flu, swine flu, zica virus, ebola virus, nepa virus and the recent entry is corona. May be it is because of changed living environment due to rising pollution or the increased poison levels of insecticides, pesticides etc in our food chain but happen they definitely; is the truth. Now there should be a treatment for the new disease but who will do this, is also a billion dollar question? The unnecessary bureaucratic hassles and complicacies combined with the super capital intensive procedures and protocols at the behest of WHO have made the drugs research very costly whereas it is the biggest truth that real drug discovery will always happen without a price tag as it happened in case of the world's greatest discovery, the discovery of penicillin. Same thing also happened with the discovery of insulin. These are the real big discoveries. Then why to add such big price tags as bigger as US \$ 2.6 billions on each and every new drug developed? A blatant no will be the answer. We can just imagine that if a great discovery happens of the status of the discovery of penicillin by a laboratory technician or pharmacist or a non- professional and ordinary citizen without an organizational background; it will never be able to cross the barriers of medical research regulatory created by WHO, may be it is a drug cure for a deadly disease like cancer or AIDS etc. It is a different question that the biggest truth remains on earth that drug discovery can not be stopped with restrictive legislations and the myth of solitary inventor has always been there and it will continue to live forever.

Drug discovery vs authentication: Drug discovery is no doubt a different field from drug authentication. For practical purposes both may be necessary but there should be at least separate protocols for both of them. Drug discovery is usually done by solitary inventors who use unique and real on the ground methodologies to check the efficacy, accuracy and verifiability of their formulas. At least let them report their findings somewhere and somehow. It does not sound sensible to mandatory force them to go through the ordeal of elaborate clinical trials which are programmed these days purely on corporate lines with super capital and infrastructure involvement. There are thousands and even hundreds of thousands of clinical trials going in the world today but a real great drug discovery happens only a few and definitely single digit times in hundred years or so. A poor isolated drug discoverer usually employs himself as the first guinea pig for his new drug, then uses his or her spouse as the next one, then employs his children, brethren, relatives, friends etc for the purpose. At least trials up to the stage of phase three are completed this way. Then where is the question of GCP protocols, infrastructure and organizational backup coming in between? He definitely lacks in them. If we shut his tongue perpetually and force him to get off the scene, we will be doing great injustice to humanity already plagued by devastating viral pandemics. Let a research be reported. Let a solitary discoverer be allowed to fly high on the horizons of drugs research.

Conclusion

It is an established knowledge that drugs can be classified in categories based on their therapeutic activity. There are anti-malarial, anti-tubercular, antibiotics etc. Now we have an

effective anti picorna virus drug which has also shown its efficacy against other viruses like influenza and corona (or a close relative of it). So, this is an anti-viral drug effective on more than one virus species. In this sense, it can be termed a broad spectrum antiviral drug. Such drugs, their active constituents along with their derivatives should be tried on other viral diseases and studied. Also, emphasis should be laid on differentiating drug discovery from drug authentication and both of them should be made purely scientific concerns and non capital intensive so that worthy poor solitary drug inventors do not face hassles in reporting their discoveries.

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Glossary of Abbreviations

AIDS: Acquired Immunodeficiency Disease Syndrome

FMD: Foot & mouth disease

GCP: Good clinical practice

GLP: Good laboratory practice

GMP: Good manufacturing practice

OPD: Out patient department

RNA: Ribose Nucleic Acid

UN: United Nations

WHO: World Health Organization

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