International Journal of Engineering, Science and Mathematics
Vol. 7 Issue 4, April 2018,
ISSN: 2320-0294 Impact Factor: 6.765
Journal Homepage: http://www.ijesm.co.in, Email: ijesmj@gmail.com
Double-Blind Peer Reviewed Refereed Open Access International Journal - Included in the International Serial Directories Indexed & Listed at: Ulrich's Periodicals Directory ©, U.S.A., Open J-Gage as well as in Cabell's Directories of Publishing Opportunities, U.S.A

"EFFECT OF ADDING GINGER IN MEDICAL REGIME ON HYPERCOAGULATION SUFFERING PATIENTS"

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Abstract- Many authorities related to medical practices are using aiternative medicines for treatments. Hypercoagulation to be a factor in many patients with chronic fatigue syndrome (CFS), fibromyalgia (FM), myofascial pain syndrome (MPS), and other disorders such as osteonecrosis (bone loss due to inadequate blood supply), and fetal loss.Hypercoagulation (thickened blood) results from fibrin being deposited in small blood vessels. Fibrin is the body's natural bandaid: strands of fibrin form across a defect (wound, tear) in the walls of blood vessels, forming a mesh that holds platelets and blood cells. This beneficial clotting of cellular matter and fibrin strands plugs the leak, so to speak, holding things together until the body starts to repair itself. Fibrin production is the last stage in a complex clotting process. The process itself starts off with the release of thrombin which in turn results in the production of soluble fibrin monomer (SFM), a sticky protein that increases blood viscosity. This leads to the deposit of fibrin on the endothelial cells that line the wall of the blood vessels. Under the normal conditions, it takes only a single burst of thrombin to generate a large amount of SFM which in turns produces sufficient amounts of fibrin to clot the defect. Testing of many patients diagnosed with CFS, FM, MPS shows that the thrombin-SFM-fibrin process is not working properly. Instead of a single burst of thrombin producing the amount of SFM needed, the thrombin keeps being produced at low levels. Instead of clots being formed, however, the result is that blood becomes increasingly thickened. The body's own ability to thin blood and break up clots is impaired because the fibrin smothering the endothelial cells prevents those cells from releasing heparans.There are two different ways this scenario can be played out. Ginger has gained interest for its potential to treat various aspects of cardiovascular disease, and the in vitro and animal data supporting the anti-inflammatory, antioxidant, antiplatelet, hypotensive, and hypolipidemic effects of this condiment have been reviewed (Nicoll and Henein 2009). However, human trials are less convincing and more investigations are needed . Caution when taking ginger and other herbal extracts has been suggested because of an apparent association of ginger with reported incidences of increased risk of bleeding following surgery (Chang and Whitaker 2001;Pribitkin and Boger 2001) or if taken with anticoagulant drugs such as warfarin (Heck, DeWitt, and Lukes 2000). However, the data are not conclusive (Vaes and Chyka 2000). At least one study indicates that ginger has no effect on blood pressure, heart rate, or coagulation parameters and does not interact with anticoagulant drugs such as warfarin (Weidner and Sigwart 2000). These findings were supported in a later study in which ginger was reported to have no effect on clotting status or the pharmacokinetics or pharmacodynamics of warfarin in healthy subjects (Jiang, Williams et al. 2005). An aqueous ginger extract was reported to induce a dose-dependent decrease in arterial blood pressure in a variety of animal models (Ghayur and Gilani 2005a,b).Based on recent studies, pungent constituents of ginger (Zingiber officinale) and related substances represent a potential new class of anti-platelet agents. The ability of 20 pungent constituents of ginger and related substances to inhibit arachidonic acid (AA) induced platelet activation in human whole blood was studied. This study includes the effect of adding ginger on the clotting parameters of the subjects and a significantly corrective effect was observed.

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key words- Hyper-coagulation, Ginger, Intervention, alternative medicines, Clotting time, bleeding time.

Introduction-The use of "natural" or alternative medicines has increased markedly over the last few years. More and more older adults (i.e., baby boomers) are using complementary and alternative medicine dietary supplements and herbal remedies, because in old age drug dependency is commonly required, chronic use of any chemotherapeutic agent is found health hazardous in many studies, thus this age group is interested more in alternative medications. In this era the percentage of old people is tremendously increasing in world population, hence studies and scope for alternative medicines is proportionally more today. The rhizomes of Zingiber officinale Roscoe (Zingiberaceae), commonly known as ginger, is one of the most widely used spice and condiment in this respect. It is an integral part of many traditional medicines and has been extensively used in Chinese, Ayurvedic, Tibb-Unani, Srilankan, Arabic, and African traditional medicines, since antiquity, for many unrelated human ailments including common colds, fever, sore throats, vomiting, motion sickness, gastrointestinal complications, indigestion, constipation, arthritis, rheumatism, sprains, muscular aches, pains, cramps, hypertension, dementia, fever, infectious diseases, and helminthiasis. The putative active compounds are nonvolatile pungent principles, namely gingerols, shogaols, paradols, and zingerone. These compounds are some of the extensively studied phytochemicals and account for the antioxidant, anti-inflammatory, antiemetic, and gastroprotective activities. A number of preclinical investigations with a wide variety of assay systems and carcinogens have shown that ginger and its compounds possess chemopreventive and antineoplastic effects. A number of mechanisms have been observed to be involved in the chemopreventive effects of ginger. The oleoresin (i.e., oily resin) from the rhizomes (i.e., roots) of ginger contains many bioactive components, such as [6]-gingerol (1-[4′-hydroxy-3′- methoxyphenyl]-5-hydroxy-3-decanone; which is the primary pungent ingredient that is believed to exert a variety of remarkable pharmacological and physiological activities. Although ginger is generally considered to be safe. the lack of a complete understanding of its mechanisms of action suggests caution in its therapeutic use.. The medicinal, chemical, and pharmacological properties of ginger have been extensively reviewed (Surh, Lee, and Lee 1998; Ernst and Pittler 2000; Afzal et al. 2001; Bode and Dong 2004; Boone and Shields 2005; Borrelli et al. 2005; Chrubasik and Pittler 2005; Chrubasik, Pittler, and Roufogalis 2005; Grzanna, Lindmark, and Frondoza 2005; Thompson and Potter 2006; Eliopoulos 2007; Shukla and Singh 2007;White 2007; Ali et al. 2008; Nicoll and Henein 2009). Over the last few years, interest in ginger or its various components as valid preventive or therapeutic agents has increased markedly, and scientific studies focusing on verification of ginger's pharmacological and physiological actions have likewise increased (Ali et al. 2008). In addition to its effects in relation to cancer, some evidence supports a protective role for ginger in cardiovascular function and a number of other disease conditions. Ginger has gained interest for its potential to treat various aspects of cardiovascular disease, and the in vitro and animal data supporting the anti-inflammatory, antioxidant, antiplatelet, hypotensive, and hypolipidemic effects of this condiment have been reviewed (Nicoll and Henein 2009). However, human trials are less convincing and more investigations are needed (Nicoll and Henein 2009). Caution when taking ginger and other herbal extracts has been suggested because of an apparent association of ginger with reported incidences of increased risk of bleeding following surgery (Chang and Whitaker 2001;Pribitkin and Boger 2001) or if taken with anticoagulant drugs such as warfarin (Heck, DeWitt, and Lukes 2000). However, the data are not conclusive (Vaes and Chyka 2000). At least one study indicates that ginger has no effect on blood pressure, heart rate, or coagulation parameters and does not interact with anticoagulant drugs such as warfarin (Weidner and Sigwart 2000). These findings were supported in a later study in which ginger was reported to have no effect on clotting status or the pharmacokinetics or pharmacodynamics

of warfarin in healthy subjects (Jiang, Williams et al. 2005). An aqueous ginger extract was reported to induce a dose-dependent decrease in arterial blood pressure in a variety of animal models (Ghayur and Gilani 2005).

In some studies it is found that administration or consumption of standardized ginger extract decreased aortic atherosclerotic lesion areas, plasma triglycerides and cholesterol, low-density lipoprotein (LDL)-associated lipid peroxides, and LDL aggregation in mice (Fuhrman et al. 2000). In rabbits that were fed a high-cholesterol diet, administration of ginger extract resulted in a significant anti-hyperlipidemic effect and a lower degree of atherosclerosis compared to the group that was fed cholesterol alone (Bhandari, Sharma, and Zafar 1998). Importantly, ginger powder (3 g/day in 1-g capsule 3xd) significantly lowered lipid levels in volunteer patients in a double-blind, controlled clinical trial study (Alizadeh-Navaei et al. 2008). Triglyceride and cholesterol were substantially decreased as was LDL levels compared to placebo group. Notably, the high-density lipoprotein (HDL) level of the ginger group was higher than that of the placebo group, whereas the very-low-density lipoprotein (VLDL) level of the placebo group was higher than that of the ginger group (Alizadeh-Navaei et al. 2008). Dried ginger powder (0.1 g/kg BW, per oral administration [p.o.] for 75 days) significantly lowered (50%) the development of atheroma in the aorta and coronary arteries of rabbits that were fed cholesterol (Verma et al. 2004). This effect was associated with decreased lipid peroxidation and increased fibrinolytic activity with ginger, but blood lipid levels were not different from control animals (Verma et al. 2004). Another compound isolated from ginger, (E)-8 β,17-epoxylabd-12-ene-15,16-dial, was reported to inhibit cholesterol biosynthesis (Tanabe et al. 1993), and ginger meal (1%) decreased serum cholesterol levels significantly (Dias et al. 2006). Ginger was also reported to slightly reduce retinoid-binding protein mRNA expression levels in liver and visceral fat in male rats that were fed cholesterol to induce hyperlipidemia (Matsuda et al. 2009). These results hint that ginger consumption might improve lipid metabolism (Matsuda et al. 2009). An evaluation of the antiplatelet activity of 20 pungent constituents of ginger revealed that [8]-paradol was the most potent COX-1 inhibitor and antiplatelet aggregation agent (Nurtjahja-Tjendraputra et al. 2003). [8]-gingerol and [8]-shogaol were also found to be effective antiplatelet aggregation agents (Nurtjahja-Tjendraputra et al. 2003). Ginger and nifedipine (a calcium-channel blocker) were reported to have a synergistic effect on antiplatelet aggregation in normal human volunteers and hypertensive patients (Young et al. 2006). Ginger oil (24% citral) effectively lowered spontaneous or prostoglandin F2-alpha (PGF2-alpha)-2α-induced rat myometrial (uterus) contractility, and increases in external calcium concentration reversed the relaxant effects of ginger oil (Buddhakala et al. 2008). Ginger compounds have been reported to directly stimulate myocardial sarcoplasmic reticulum (SR) calcium uptake (Antipenko, Spielman, and Kirchberger 1999; Maier et al. 2000), but its therapeutic use in treating heart failure has not been advocated (Maier et al. 2000).

Polycythemia vera is a condition caused by the excess production of red blood cells in the bone marrow. Production of other types of blood cells such as white blood cells and platelets may also increase but it is primarily the increase in red blood cells that is responsible for the thickening of blood. This thickening of blood can have serious consequences leading to complication such as heart attack and stroke. Polycythemia vera is a rare blood disorder and develops gradually. It is often diagnosed accidentally when abnormalities in red blood cell levels show up in blood reports. While it can prove to be fatal if it is left untreated, proper medical care can ensure that a person leads a normal life with few problems associated with the condition. Thrombosis or blood clotting, resulting in heart attack, stroke or damage to other parts of the body is common problem associated with the disease.Some other medical conditions are also related with hyper-coagulation related problems as -ACS,

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PCI, atrial fibrillation, stroke, and valvular heart disease, atrial fibrillation, left-ventricular thrombus, cerebral embolism, venous embolism, or pulmonary embolism) congestive heart failure , persons taking HRT,Thrombotic Thrombocytopenic Purpura/Hemolytic Uremic Syndrome.

Based on the previous studies a hypothesis is designed to assess the role of Ginger in preventing/reducing coagulation of blood-

"A Study to assess the Ginger as coagulation –preventing agent in some Aspirin dependent patients of Heart Failure , atrial fibrillation , Hemolytic Uremic Syndrome Polycythemia Vera and other hyper-coagulation related problems"

Material & Methodology-

Subject Size-Experimental subjects- 14 [Group 2] +14 [Group 3] total (28) Patients of Herat Failure, Haemolytic Uraemia syndrome /other Hyper-coagulation related disorder.

Controls- 28 , who are randomly selected and demographically matched with patients in all means including medications , but not taking Ginger Juice as remedy.

Study area- Bilaspur , Raipur city and outskirt areas

Study Time- August 2012 to November 2017

Objectives – Two studies were designed to assess the Anticoagulation effect of Ginger

Three groups were formed –

Group 1- 25gm Ginger powder (capsulated) plus 5 mgs Aspirin (two divided doses) and single dose Warfarin (2.5 mgs)

Group -2 5 mgs Aspirin in Two divided doses and one dose of warfarin (2.5 mgs)

Group -3 5 mgs Aspirin in Two divided doses and one dose of warfarin (2.5 mgs) and Placebo dose (Empty capsule)

- **Profile of the subjects**- The experimental and control subjects were all patients of hyper-coagulation disease, taking Warfarin and Aspirin as medicines. The Experimental group was given Ginger juice as part of medicine and effects were observed on biochemical parameters. And symptoms.

Duration of Intervention of Ginger as remedy-three weeks /individual

- The study subjects were selected on the basis of clotting parameters and symptoms like –Headaches, Dizziness, Itching sensation, Reddish skin, Breathlessness, A tingling or burning sensation in the limbs and extremities, Numbness or weakness in the limbs and extremities, Bloating in the upper left abdomen caused by an enlargement of the spleen, Fatigue. After completing formalities of medical ethics , they were all in strict supervision of Nature Care Centre and Cardiac centre, KIMS, Bilaspur.
- Age range -38-77 for both the groups.

Objectives –The following biochemical parameters were assessed in subjects of all three groups-

- Clotting time by Capillary Glass Tube method-it is expected to have fast clotting time
- Bleeding Time – By Ink Spot Method, it is expected to have lesser bleeding time
- Serum Fibrinogen Level-By using Auto analyzer Star 21 , by using Kit of Span diagnostics , because in diseases related with hyper-coagulation , it is expected to have high serum fibrinogen level
- Ca:P level, as the complex is higher in conditions related with hyper-coagulation thus the serum level of Ca:P complex was estimated
- Serum Homocysteine Level by Auto-analyzer Star 21, because hyper Homocyatenemia is related with hyper-coagulation
- Total Platelet count by Differential Haematology Blood Cell Counter Apparatus, hyper-coagulation is related with higher serum count of platelets
- Serum Creatinine Level, high level is related with hyper-coagulation, by using Biochemical Analyser Star 21 , by using the Kit of Span Diagnostics.
- C-reactive protein level-CRP test by analyser, higher level is correlated with hyper-coagulation
- Platelet aggregation factor-by sending samples to Abhay 's Pathology lab, Bilaspur.
- C-Reactive Protine as it's higher level is related with diseases of hyper-coagulation.
- Total Lipid Profile as Serum Lipid level is significant factor for affecting blood's clotting profile and some previous studies indicate that ginger has Hyper-lipidemia correcting capacity, thus all the lipid parameters are analysed by Auto-analyzer Star 21 of subjects of all three groups.
- Total Blood Haemoglobin level as in some hyper-coagulation like diseases serum Hg level is affected as Haemolytic Uremic Syndrome, by Acid Haematin method.
- Serum Lactate Dehydorgenase-as some studies showed it's higher level in hyper-coagulation by biochemical analyser.

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Table-1

Profile of the Patients

Sr No	Age slot	Numbers	Cause of Hyper coagulation	Complications
1.	**38-48**	**3**	**Atrial Fibrillation**	left-ventricular thrombus, ,
2.	**49-58**	**4**	**Vulvar Disease**	cerebral embolism
3.	**59-68**	**5**	**COPD**	venous embolism
4.	**68+**	**2**	**Cardiac stroke**	pulmonary embolism

Table-2

The Biochemical parameters assessed –

Sr No	Parameters	Group1	Group 2	Group 3	t
1.	Clotting Time	12.37 min	6.77 min	8.1 min	
2.	Bleeding time	5.13 min	2.51 min	3.36 min	
3.	Ca:P complex	32 mg /dL	72 mg /dL	61 mg/dL	
4.	Fibrinogen Level	220 mg/dL	433 mg/dL	302mg/dL	
5.	Platelet count	334233 / microliter	5100455 / microliter	459000 / microliter	
6.	Platelet aggregation factor	22%	47%	34%	
7.	Prothrombin time	9 seconds	6 seconds	7 seconds	
8.	Homecysteine level	10.3 µmol/L	14.02 µmol/L	12.11 µmol/L	
9.	C protein	2.91 mg/L	6.44 mg/L	7.12 mg/L	

10	S protein	61 U/dL	79 U/dL	66 U/dL	
11	Serum Creatinine	0.37mg	1.56mg	0.89mg	
12	PTT Partial Thromboplastin time	39 seconds	12 seconds	28 seconds	
13	Haemoglobin	11.2 gm%	13.2gm%	10.3 gm%	
14	Lactate Dehydrogenase	96 U/L	248 U/L	199 U/U	

TABLE-3

THE LIPID PROFILE ANALYSIS OF ALL THE THREE GROUPS

Lipid Constituents	(mean)			Chagne in per-centage value	Group1st and group 2nd observation (df =54) t value
	Group 1st observation	Group 3rd observation	Group 2nd Observation		
Cholesterol (mg/ml)	1.64 (±0.18)	1.90 (±0.10)	2.37 (±0.07)	↑ 45%	4.42 *,**
Triglyceride	1.22 (±0.08)	1.30 (±0.28)	1.34 (±0.28)	↑ 10%	1.18 NS

(mg/ml)					
HDL (mg/ml)	0.51 (±0.09)	0.46 (±0.09)	0.31 (±0.03)	↓ 39%	5.84 *,**
LDL (mg/ml)	0.93 (±0.19)	1.19 (±0.17)	1.78 (±0.10)	↑ 93%	7.46 *,**

NS = Not Significant.

* P<0.05 level, **P<0.01 level. SD values showed in parenthesis.

Study-2

In some randomly selected patients of hyper-coagulation due to various causes, the effect of ginger intervention was observed on their related biochemical parameters before and after intervention (After three weeks).

Sr No	Parameters	After	Before
1.	Clotting Time	11.66 min	7.21 min
2.	Bleeding time	5.48 min	3.11 min
3.	Ca:P complex	67 mg /d L	81 mg /dL
4.	Fibrinogen Level	253 mg/dL	411mg/dL
5.	Platelet count	434233 / microliter	5100455 / microliter
6.	Platelet aggregation factor	39 %	47 %
7.	Prothrombin time	9 seconds	6 seconds
8.	Homocysteine level	12.32 µmol/L	15.43 µmol/L

9.	C protein	4.56 mg/L	6.09 mg/L
10.	S protein	58 U/dL	69 U/dL
11.	Serum Creatinine	0.32mg	1.33 mg
12.	PTT Partial Thromboplastin time	37 seconds	10 seconds
13.	Haemoglobin	10.2 gm%	12 .2gm%
14.	Lactate Dehydrogenase	166 U/L	241 U/L

Result & Discussion-The above findings show that ginger compounds and their derivatives are more potent anti-platelet agents than aspirin under the conditions described in this study. The clinical data undoubtedly indicate that ginger is at least as effective as anti clotting agent mechanisms are lacking, but no reports indicate that ginger has any adverse side effects or that it can worsen illness in patients. Ginger also appears to reduce cholesterol and improve lipid metabolism, thereby helping to decrease the risk of cardiovascular disease and diabetes. The 1st group taking ginger had shown better biochemical clotting related parameters, after intervention period especially in terms of clotting and bleeding time and platelet count. In summary, ginger has been reported to possess diverse pharmacological properties, although its specific biological targets are largely unknown and remain to be determined. However, in spite of the lack of specific mechanistic information, use of ginger appears to be safe and its effects are mighty and amazing in its many applications. The 1st group found that administration or consumption of standardized ginger extract decreased hyper-coagulation related symptoms, also plasma triglycerides and cholesterol, low-density lipoprotein (LDL)-associated lipid peroxides, and LDL aggregation in subjects. However a detailed community based work is required to conform the conclusions.

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