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Pharma, Drug Discovery,
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Antidiabetic Herbal Capsule

Types of Machinery of Transcription

Highlights

Drug Compliance among People

A Detailed Review on Plant Material

Discovering Thoughts, Inventing Future

VOLUME 21 ISSUE 2 VERSION 1.0



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PHARMA, DRUG DISCOVERY, TOXICOLOGY & MEDICINE



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Effectiveness of an Awareness Programme on Drug Compliance among People with Selected Chronic Diseases

By Navaneetha.M

Abstract- The compliance to drug treatment leads to the prevention of deaths from the disease. Nurses play a very important role in the adherence to treatment by patients. The study aims at exploring the level of drug compliance among people with chronic illness (hypertension and diabetes mellitus), factors that influence the decision of the person and evaluates an awareness programme on the identified issues. The study used a Survey and Evaluative Approach with survey and quasiexperimental design. Purposive sampling was used to collect data from Marne, Athrady, Herebettu which are rural areas and Malpe area of Manipal which is an urban area. Among 23535 population surveyed a total of 1286 (602 urban and 684 rural) samples with the disease and undergoing treatment were identified. 328(184 urban and 144 rural) people who were not complying to drugs were given awareness programme. The tools used were Demographic performa, Morisky scale, Srivastava Socioeconomic scale, scale for Health status (SF-36) and a scale to assess factors. The study was based on the Rosentoch's, Becker and Maiman's Health Belief model.

Keywords: drug compliance, moriskyscale, srivastava socioeconomic scale, scale for health status (SF-36), health belief model, awareness programme.

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Navaneetha. M

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Keywords: drug compliance, moriskyscale, srivastava socioeconomic scale, scale for health status (SF-36), health belief model, awareness programme.

1. INTRODUCTION

Medication compliance is defined as the extent to which a patient takes the medication as prescribed. There are multiple studies in the literature that report non compliance rates of 30% to 50% or higher based on the class of agents and population studies, when medication was to be taken over a long period, compliance rates dropped dramatically to approximately 50% for either prevention or cure. The compliance to drug treatment leads to the prevention of deaths from the disease. In India studies of this nature are very few and hence the problem has to be explored.

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A cross-sectional study was conducted by Cesar I. Fernandez-Lazaro et al, in primary healthcare centers of Spain which included 299 adult patients with ≥ 1 chronic condition(s) and prescribed medication. The study used Morisky-Green-Levine questionnaire to assess medication adherence by interviews. 55.5% were the proportion of adherent patients to treatment. The independent factors assessed were Older age, lower number of pharmacies used for medication refills (0.65, 95% CI 0.47–0.90), having received complete treatment information (3.89, 95% CI 2.09–7.21), having adequate knowledge about medication regimen (4.17, 95% CI 2.23–7.80), and self-perception of a good quality of life (2.17, 95% CI 1.18–4.02). To achieve appropriate levels of adherence tailored multifaceted interventions are required on the multidimensional factors found in this study, particularly those related to patients' education and their information needs.

The scope of the study developing a generic, individualized adherence programme for chronic medication users was to describe the background for and content of an adherence counseling programme with a specific focus on an individualized, multi-dimensional adherence model for patients with a potential adherence problem (a so-called individualized systems model).

An intervention programme based on WHO's systems model for adherence was developed for implementation in primary health care and tested in a development project in Danish pharmacies in 2004-2005 by 27 patients in three pharmacies and 4 GP practices. Data were collected from the participants by registration forms, questionnaires, and focus groups. Since the programme was to support patients within the self-management process regarding choice and implementation of medication treatment, various strategies were used and different theoretical assumptions and choices made before fixing the study. The strategies used include differentiating the differing kinds of non-adherence, a model for stages of change, self-efficacy, narratives, motivating interviewing strategies and training techniques. The strategies and theoretical reflections led to the formation of a counselling programme, which was tested in two forms, a basic and an extended version - provided by either a pharmaconomist or a pharmacist. Besides, the results

include a description of how the WHO-model is transformed into an individualized counseling model. According to WHO, non-adherence should not be viewed as an isolated, single-factor problem, but rather as a multi-dimensional problem not determined

exclusively by patient factors, as is seen most often in adherence research. WHO's systems model aims to analyze and provide explanations for non-adherence on a societal and health policy level in a broader sense.

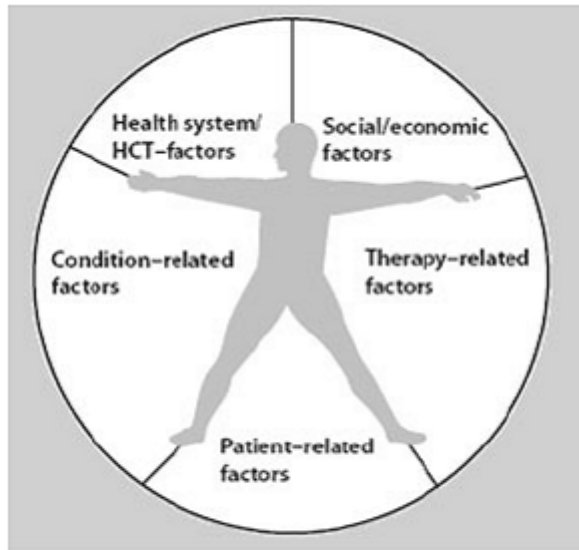


Figure 1: The five dimensions of adherence as suggested by the World Health Organisation

The programme identifies potential non-adherence, analyses the character of the issues identified, such as drug-related problems, explores patient resources and provides concordance-based follow-up sessions and individually based interventions.

The model developed and used as a template for the entire programme was called the individualized systems model. It emerged from the transformation of the WHO model into an individualized counseling model.

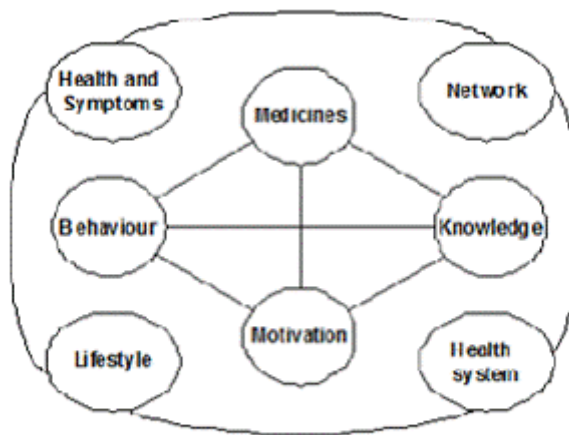


Figure 2: The individualised systems model

Usha Malagi, Rama Naik and Ramesh Babruwadin in their study on Knowledge Practices and Life Style Factors of Type - 2 Diabetics has found that the life style factors such as foods restricted and specially included, vices prevalent, exercise behavior and knowledge and practices of 50 type-2 diabetics were assessed using a pretested structured questionnaire. Diabetics restricted the foods such as rice, roots and tubers, sweets and fruits. The foods were specially included for the management of disorder by majority of diabetics (72%). The food which was specially included

was green leafy vegetables, bitter gourd, salads, ragi and spices. The habits practiced by men were smoking (14%), drinking alcohol (48%) and tobacco chewing was seen in very few men and women. Exercise was done by half of the diabetics (56%) and half of the exercising subjects had started exercise only about a year back. About 30 and 16% diabetics had poor knowledge of diabetes practices. Thus, the diabetics need education to improve the knowledge and practices for the proper management of disorder.

The EAPACUM-HTA study in Spain at 40 primary care centres conducted for 6 months with newly diagnosed or uncontrolled hypertension included 250 patients. They were given an electronic monitor for measuring compliance (monitoring events medication system). Compliance observed was 74% and 92% in control group and intervention group. (95% CI 81.2-94 and 80.7-98.3; $P=0.0001$). The number need to treat to avoid one case of noncompliance was 5.6 patients. The programme was found effective in improving compliance in arterial hypertension.

Nurses play a very important role in the adherence to treatment by patients. In the paper Nursing Care Management and Responsibility it is stated that: Improving patient compliance with treatment orders through health education and extending care to

all patients, education will help patients to improve drug compliance.

The study aims at exploring the factors that influence the decision of the person suffering from chronic diseases, to comply with the regular drug regimen prescribed for them. The study also recommends means to organize an awareness programme on the identified issues. Thus ultimately contributing to one of the goal set by WHO i.e. to reduce death rates in chronic diseases.

The objectives of the study are to:

1. Assess the level of drug compliance and identify the factors influencing it
2. Plan and evaluate the effect of an awareness programme on drug compliance

II. METHODOLOGY

Research Approach: Survey and Evaluative Approach

Phases	Design	Instrument	Plan of data analysis
I	Survey	Demographic variables Morisky scale-scale to assess level of drug compliance	Percentage, Prevalence rate, mean, chi-square
		Scale on Health status(SF-36) Scale on complexity of medication, patient knowledge, social support and patient provider interaction	Multiple logistic regression, other tests
II	Quasi experimental	Morisky scale and scale on knowledge	Non-parametric tests

Setting and Population: The target population of the study comprised of the people with the disease conditions and undergoing treatment in the selected

rural and urban areas ie Marne, Athrady, Herebettu which are rural areas and Malpe area of Manipal which is an urban area.

a) Sample and Sampling technique

Purposive sampling was used

Area	Population
Rural	
Kidiyoor-Malpe	4546
Herebettu	2302
Marne	2734
Alevoor	2101
Total	11683
Urban	
Kalmady-Malpe	5152
Kodavoor A-Malpe	6700
Total	11852

Among this a total of 1286 (602 urban and 684 rural) samples with the disease and undergoing treatment were identified. 328(184 urban and 144 rural) people who were not complying to drugs were given awareness programme.

b) Procedure for Data Collection

House to house survey was done and people with either of the diseases taking any system of medicine were given the questionnaire. Those identified with drug non compliance was given teaching and there

level of compliance and knowledge was assessed after 15 days.

Data analysis was done based on the objectives and hypotheses stated in the study by using descriptive and inferential statistics

c) Description of tool

The following tools were used Demographic performa, Morisky scale, Srivastava Socioeconomic scale, scale for Health status (SF-36) and a scale to assess factors.

The Demographic performa consisted of variables including age, sex, education, occupation, place of residence, socio economic status, nature of disease and nature of treatment.

Morisky scale was used to assess the level of drug compliance which is a self administered tool. It includes 4 statements with Yes/no. It is measured as 0- sure high adherence, 1-2- Medium adherence, 3-4- low adherence.

The Srivastava Socioeconomic scale was used in the study.

The factors were assessed with scales for Health status (SF-36) which is a scale with 36 questions to assess a person's health status and one prepared with statements on knowledge of patient, medical complexity, social support and patient-provider interaction. Each statement consists of 3 options- always, sometimes, never. This tool was purchased from author.

The *content validity index* was 0.86.

The reliability of the tools was found to be $\alpha=0.8231$ by Cronbach alpha method.

III. CONCEPTUAL FRAMEWORK

The study was based on the Rosentoch's, Becker and Maiman's Health Belief model. This model was developed to provide a framework for understanding why some people take specific actions to avoid illness, whereas others fail to protect themselves. The model was designed to predict which people would and would not use preventive measures and suggest interventions that might reduce client's reluctance to assess health care. There are three major components of the health belief model: individual perceptions, modifying factors and likelihood of action. In addition uses of cues to action such as mass media campaigns, advice from others, illness of family members or friends and newspaper and magazine article may help to motivate clients to take action.

The health belief model is beneficial in assessing health protection or disease prevention behaviours. It is also useful in organizing information about clients' views of their state of health and what factors may influence them to change their behavior. The model, when used appropriately provides organized assessment data about client's abilities and motivation to change their health status. Health education programs can be developed to fit the clients.

In this study the first component was individual perception which is the non compliance to drugs of hypertension and diabetes mellitus.

The second component was modifying factors which include the demographic variables and structural variables. The demographic variables include age, sex, socioeconomic status and nature of treatment. The structural variables are the factors which will influence the drug compliance.

The third component is likelihood of action, which includes perceived benefits minus perceived barriers for preventive action. In this study the benefit will be the gain in knowledge by the client which will lead to change in behavior. The barriers may be the number of drugs taken and socioeconomic status, etc. In addition to this the components on cues to action is the health awareness programme which can motivate the client to take action.

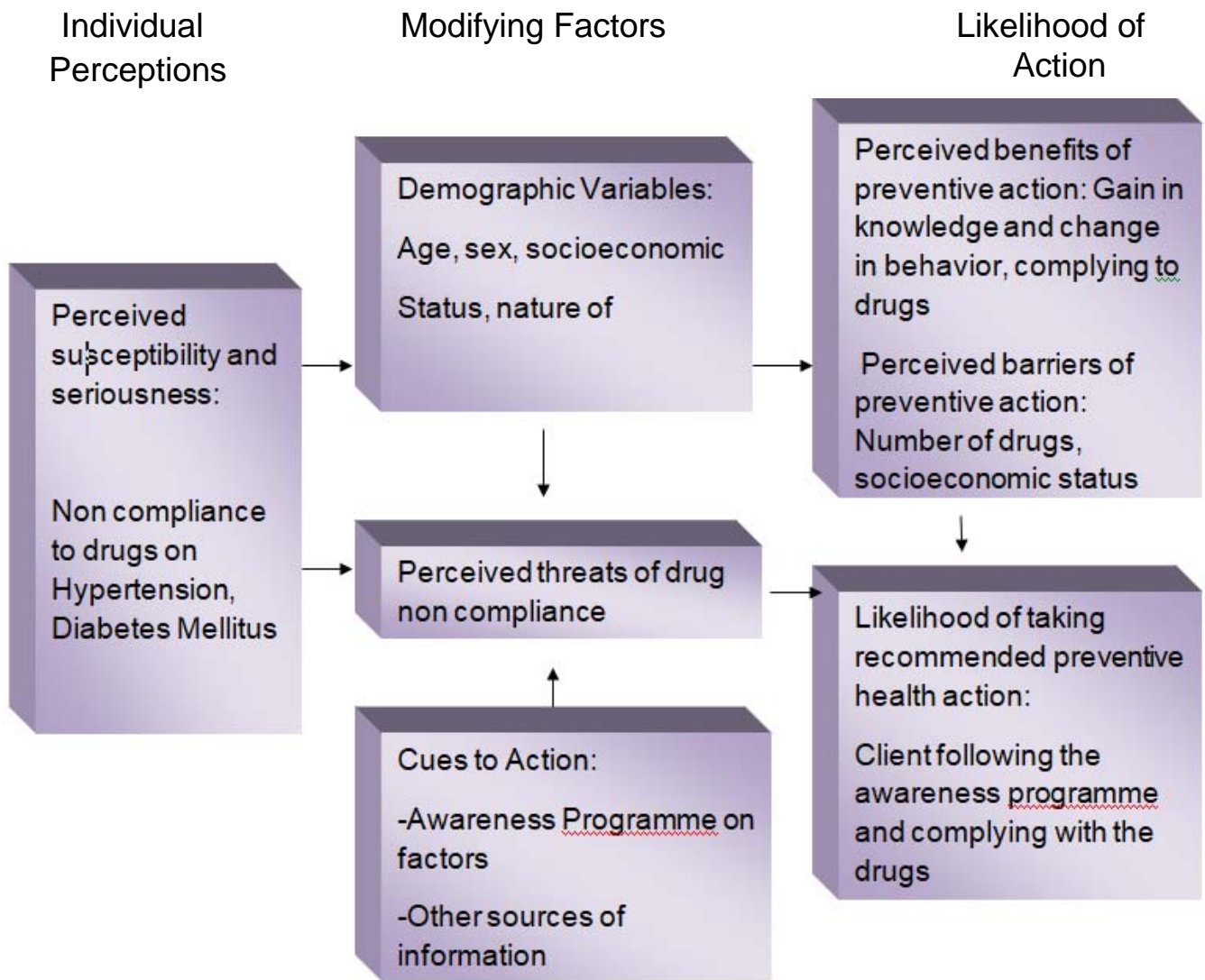


Figure 3: Conceptual Framework based on Rosenstoch's and Becker and Maiman's Health Belief Model

IV. RESULTS

Table-1: Frequency and percentage distribution of demographic characteristics

n = 1286

Sample characteristics	Area			
	Rural (n=684)		Urban (n=602)	
	Frequency	Percentage	Frequency	Percentage
Age				
30-40	53	7.75	128	21.26
41-50	246	35.96	182	30.23
51-60	292	42.69	174	28.90
61 and above	93	13.60	118	19.60
Sex				
Male	296	43.27	284	47.18
Female	388	56.73	318	52.82
Socio Economic status				
Low	413	60.38	246	40.86
Medium	265	38.74	312	51.83
High	6	0.88	44	7.31

The data represented in Table-1 show that, out of 1286 subjects, 684 (53.19%) belonged to rural area and 602 (46.81%) belonged to urban area. 246 (42.69%) belonged to 51 – 60 years of age in rural area and in urban area 182(30.23%) belonged to 41-50 years. In both areas most of the samples were females i.e. 388 (56.73%) and 318 (52.82%) respectively. In rural

413(60.38%) belonged to the low socioeconomic status and in urban 312(51.83%) belonged to the medium category.

The sample was classified as low, medium and sure adherence to medication based on the details of Morisky scale.

Table -2: Level of drug compliance n=1286

Level of Drug Compliance	Area			
	Rural (n=684)		Urban (n=602)	
	Frequency	Percentage	Frequency	Percentage
Sure Adherence	540	78.95	418	69.44
Medium Adherence	90	13.16	95	15.78
Low Adherence	54	7.89	89	14.78

The data in Table-2 describes the sample in terms of their level of drug compliance. In rural area 540(78.95%) were adhering to drugs were as in urban area only 418(69.44%) were adhering to the drugs.

There was a significant association between area and level of drug compliance. ($\chi^2=19.087$, $p<0.001$)

Among the factors identified that is Knowledge, Medical complexity, Social relations (Husband/wife, Family member, Friends) and Patient provider interaction system of medicine, medication prescribed. , SF 36 only factors of knowledge ($\chi^2=113.081$, $p<0.001$), medical complexity ($\chi^2=90.814$, $p<0.001$) and relation of husband or wife ($\chi^2=7.831$, $p=0.02$) were significant. It was also found that there was a significant relationship between the area and factors for knowledge of medicines taken ($Z=-2.708$, $p=0.007$), relationship between sample and family member and

friends to motivate to take medicines ($Z=-4.668$, $p<0.001$, $Z=-4.527$, $p<0.001$) and the health status score SF-36($Z=-2.117$, $p=0.034$).

Further a regression analysis was done with the factors associated and it is concluded that there is a relationship between knowledge (OR= 1.28, CI- 1.20-1.35, $p<0.001$), medical complexity (OR= 1.14, CI- 1.10- 1.19, $p<0.001$) and the people getting drug metformin (OR=0.278, CI- 0.08-0.88, $p<0.03$) with sure complying of drugs. In medium compliance there was a relation with hypertension (OR=2.70, CI- 1.39-5.24, $p=0.003$), diabetes (OR=2.84, CI-1.42-5.68, $p=0.003$), knowledge (OR=1.14, CI-1.07-1.22, $p<0.001$) and medical complexity (OR=1.05, CI-1.01-1.10, $p=0.16$). Hence it is concluded that knowledge and medical complexity were the two factors affecting drug compliance.

Table -3: Association between level of drug compliance among experimental and control groups in post test n=328

Group	Level of drug compliance			χ^2	df	p
	sure	medium	low			
Experimental	155	7	2	282.14	2	<0.001
Control	3	121	40			

Table -4: Association between level of drug compliance in pre and post test in Experimental group n=164

Pretest	Level of drug compliance Posttest			χ^2	df	p
	Sure	Medium	Low			
Medium	92	91	2	57.00	2	<0.001
Low	66	37	40			

Both tables show that there is a significant difference between level of drug compliance after the teaching and counseling programme. Further the knowledge aspect which was relating to the need for medicine intake was also assessed in pre and posttest

of experimental group, Wilcoxin's sign rank test gave a significant relationship. ($Z=-11.810$, $p=<0.001$).

There was also a significant difference between the posttest knowledge of experimental and control group ($Z=-7.540$, $p=<0.001$)

Table -5: Relation between level of drug compliance and knowledge in posttest (N=328)

	Level of drug compliance Posttest			χ^2	df	p
	Sure	Medium	Low			
Post test knowledge	158	128	42	66.728	2	<0.001

There was a relationship between the knowledge and level of drug compliance in posttest of experimental group ($\chi^2=66.728$, $p<0.001$).

With all the above it is concluded there was a difference in the level of compliance between pretest and posttest

V. DISCUSSION

The study on Self-Reported Morisky Score for Identifying Nonadherence with Cardiovascular Medications reports that the Morisky medication adherence scale is a commonly used adherence screening tool. It is composed of 4 yes/no questions on past medication use patterns. Forty-nine of 377 (13%) patients were categorized as non adherent; however, only 12 (3%) patients had Morisky scores suggesting a high likelihood of non adherence (3 or 4). *The present study has identified 114(13.64%) medium and 98(11.72%) low out of 836 hypertensive patients.*

In a study conducted by glycemic control and medication compliance in diabetic patients in a pharmacist managed clinic in Hong Kong; non compliant patients were assessed by nurses and sent to the pharmacist. The clients had to visit the clinic three times. Out of 95 patients, 91 gave complete data. The compliance rate at the beginning and at the end of third visit was 41.3 ± 25.6 and 97.8 ± 1.6 , $p<0.005$. In the current study the diabetes with level of compliance and low were 116. The reasons for non compliance stated in the study is similar to the study findings with Forgetfulness 61.5%, Adverse effects 25.3%, Wrong belief about treatment 8.8%, Not realizing that the treatment had been changed 6.6% and others 2.2% which are the points assessed under knowledge and medication complexity. These concepts had a scale score of mean 14.55 ± 3.541 standard deviation in rural and 15.27 ± 4.323 in the urban area and for medication complexity 20.31 ± 5.859 in rural and 20 ± 6.433 in urban.

Another supporting study related to negative medication belief conducted in Kuwait as a prospective cross-sectional study for patients treated for chronic illnesses in the Ministry of Health primary care clinics was to identify self-reported adherence to medications, beliefs, and perceived sensitivity toward medications. Of the response rate of 68.1%. 56.7% were male, 73.7% were married, 53.3% were non-Kuwaitis, and 49.4% had low income and had a mean of two comorbid illnesses. They had indicated taking an average of four prescription medicines to treat them. A structural equation model analysis showed that the following are negatively impacting adherence to medications: higher

negative beliefs toward medications (beta = -0.46), marital status (being unmarried; beta = -0.14), nationality (being Kuwaiti; beta = 0.15), lower education level (beta = -0.14), and higher illness severity (beta = 0.15).

A study on Compliance and knowledge of hypertensive patients attending PHC centres in AL-Khobar, Saudi Arabia was a cross-sectional study of all hypertensive patients (190) attending four primary health centres. The mean age was 49.9 ± 11.7 years, the overall compliance rate was 34.2% which was lower in those aged <55 years than older patients (26.2% versus 48.5%, $p< 0.001$) and among educated than illiterate (30.4% and 38.1% respectively, $p<0.001$). The knowledge level regarding the disease was very minimal as 41.6% of the patients thought that hypertension could have a permanent cure and 43.7% that medication could be stopped once control was achieved. As to the etiology 66.3% thought as emotional stress and 1.6% as heredity. Hence an education on hypertension is essential among these patients. Among the people who did not comply to medicine most of them were hypertensives ie a total of 160 and most of them were in the age group of 51-60 years in both rural and urban area. In rural the level of compliance was 63(43.75%) and urban 56(30.43%). The females did not comply to drugs in both groups and they belonged to medium socioeconomic status.

In the study the multilevel compliance challenge; it is stated that compliance is a complex behavioural pattern strongly influenced by the environments in which the patients live, healthcare providers practice and health care systems delivery of care. The health care providers including pharmacists, nurses, psychologists etc who are involved in primary and secondary prevention play a role in enhancing compliance by interpreting recommendations, educating and motivating patients, monitoring responses to recommended behaviours and providing feedback. Maximum use of these services should be made by patients to overcome non compliance to drugs. Multilevel approach of education and behaviour change is important like consumer health education, provider education, etc.

In a study on assessment of impact of medication counseling on patients' medication knowledge and compliance in an outpatient clinic in South India explains that there is an improvement in the compliance among the group of patients who were counseled against the usual care group. (92.29 ± 4.5 and 84.71 ± 11.8) Knowledge level of the counseled group also showed an improvement (13.82 ± 1.8604 and

11.78±3.5037). The current study also shows a significant difference in patient's level of compliance after an awareness programme ($\chi^2=282.14$, $p<0.001$), the study also reveals a significant difference in knowledge levels ($Z= -7.540$, $p<0.001$).

VI. CONCLUSION

The study concludes that medication compliance differs in urban and rural populations, reasons mainly being knowledge and medical complexity. It also found appropriate awareness programme conducted can bring a change in the compliance.

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Fabrication and Characterization of Porous Nanohydroxyapatite/Chitosan-Cellulose Composite Scaffold for Biomedical Application

By S.Nagalakshmi, G.M. Pavithra, R.Tharani, Vaddarapu Ashok & Fathima Azra Zainul Afker

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Methods: Several scaffold formulations are prepared (S1, S2, S3, and S4) using various polymers. The prepared scaffold was studied for their weight loss, swelling ability, X-Ray Diffraction (XRD), Scanning Electron Microscopy (SEM) Electron Dispersive X-Ray Analysis, Transmission electron microscopy (TEM), Fourier Transform Infrared Spectroscopy (FT-IR), optical microscopy, *in vitro* release studies, and *in vitro* antimicrobial studies.

Keywords: bone grafting, scaffolds, hydroxyapatite, ofloxacin, chitosan.

GJMR-B Classification: NLMC Code: QV 704



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Fabrication and Characterization of Porous Nanohydroxyapatite/Chitosan-Cellulose Composite Scaffold for Biomedical Application

S.Nagalakshmi ^α, G.M. Pavithra ^σ, R.Tharani ^ρ, Vaddarapu Ashok ^ω & Fathima Azra Zainul Afker [¥]

Abstract- Objective: Bones are stiff structures that upkeep and guard several body parts of the physique. A medical technique entitled bone grafting substitutes misplaced bone to overhaul bone fractures that are very intricate, Otherwise, that does not cure precisely.

Methods: Several scaffold formulations are prepared (S1, S2, S3, and S4) using various polymers. The prepared scaffold was studied for their weight loss, swelling ability, X-Ray Diffraction (XRD), Scanning Electron Microscopy (SEM) Electron Dispersive X-Ray Analysis, Transmission electron microscopy (TEM), Fourier Transform Infrared Spectroscopy (FT-IR), optical microscopy, *in vitro* release studies, and *in vitro* antimicrobial studies.

Results: Four formulations (S1, S2, S3, S4) of the scaffold was formulated using the freeze-drying technique. The characterization studies indicated that formulated Scaffold (S4) showed the minimum loss of weight (2.7 %) in four weeks and thus had the lowest degradation. The swelling was similar in all the scaffold formulations due to constant hydroxyapatite and chitosan concentrations. The porosity of the scaffold formulations was identical to one another. From the report of the antibacterial activity of the formulated scaffold, it was found that the scaffold (S4) with various concentrations of 100µg, 200µg, and 400µg when compared with standard positive and negative control, showed a maximum zone of inhibition of 26mm, 32mm and 34mm respectively. Hence the prepared scaffold exhibited higher antibacterial activity.

Conclusion: Nanohydroxyapatite formulation has high biocompatibility and bioactive properties. The contagions allied with the implantation recurrently minimize the usage of biomaterials in humans. Thus, the developed scaffold would be a promising biomaterial for biomedical applications.

Keywords: bone grafting, scaffolds, hydroxyapatite, ofloxacin, chitosan.

I. INTRODUCTION

In the past two decades, tissue engineering by bone regeneration has become an alternative method used to overcome the shortcomings of conventional bone defect treatments [1]. Bones are upkeep and guard various organs of the body. Damage induces a significant decrease in the quality of our life. A medical technique called bone grafting substitutes lost bones to patchup bone fractures, which are very difficult,

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imparting substantial health hazards to a patient, or flap to cure appropriately. The grafts may be autologous, allograft, or synthetic. Many of the grafts get reabsorbed and substituted when the normal bone reconciles over some time. The doctrines in fruitful grafts include osteoconduction, osteoinduction, and osteogenesis [2].

The progress in the medical discipline has upgraded biomaterials role in substituting injured tissue, organs and enhancing their functions. Bone tissue engineering is a novel treatable practice for bone grafting [3]. The tissue engineering research is implemented mainly in two fields: osteo and dental applications. This technique implants scaffolds, which give mechanical strength in the crack zones. The scaffold remains as a momentary medium for cell multiplication until fresh tissue is entirely revived [4].

Hydroxyapatite (HAP) is one of the apatite materials that have a significant inorganic constituent of teeth and bone, which has high biocompatible and bioactive properties and hence employed in bone tissue engineering. Its flow property strength is very little than those required for bone tissue engineering materials and has a tend to migrate from implant sites. These limitations can be overwhelmed by combining hydroxyapatite with organic constituents, thus mimicking the ECM of bone [5]. The contagions allied with the implantation recurrently minimize the usage of biomaterials in humans. Bacteria trigger the patient's immune system forming a protective film by sticking onto biomaterial exterior. To avoid these complications, ofloxacin which possesses antibacterial activity, has been incorporated in this biomaterial [6]. Thus, the present research work was intended towards the formulation of nano biocomposite scaffold of hydroxyapatite-chitosan-cellulose. Five formulations namely, S1, S2, S3, S4, and S5, was developed. These five formulations are initially characterized for various properties. The optimized formulation, i.e., S5, was characterized by analytical techniques.

II. MATERIALS AND METHODS

a) Materials

Hydroxyapatite, Chitosan, Sodium Carboxy Methyl Cellulose, Carboxy Methyl Cellulose, Hydroxy

Propyl Methyl Cellulose, Ofloxacin and acetic acid were purchased from Sastha Scientific Services, Chennai.

III. METHODOLOGY

a) Preparation of Hydroxy Apatite Nanoparticles

The orthophosphoric acid solution was added drop by drop into calcium hydroxide solution under magnetic stirring at 70°C for 3 hours. The mixture is stirred until a clear and homogenous solution formed, and then sodium hydroxide solution was added to this solution until pH value was maintained at 10. The white precipitates were left for 4 hours. The obtained nanoparticles were parted, clarified with deionized water, and dried under ambient atmosphere. It was then heated in an electric furnace at 700°C to obtain pure nanoparticles [7,8].

b) Fabrication of Scaffold

Hydroxy Propyl Methyl Cellulose (HPMC) and 100 mg of ofloxacin drug were dissolved in water using a mechanical stirrer until a homogenous solution was formed. Secondly, chitosan was solubilized in 2% acetic acid, which was instilled dropwise into the HPMC mixture. It is then mixed at 500 rpm. These mixtures were added to the above-formed nanoparticles. The stirring is kept for 24hrs and, the gel formed was then transferred into the tissue culture dish and cooled at -24°C for 24 hrs and lyophilized to form scaffolds. These scaffolds were cross-linked with CaCl₂ solution for 30 minutes, followed by sopping in ethanol for 10 minutes. Finally, the scaffold was clarified with water and another timely ophilized [9,10].

c) Preparation of Five Formulations of Scaffold

By experimenting with different polymers, five formulations of the scaffold was prepared namely, S1, S2, S3, S4, and S5.

IV. CHARACTERIZATION STUDIES

a) Calibration Curve of Ofloxacin

The calibration curve of ofloxacin was performed using various concentrations of ofloxacin, as given in Figure no.1 [11].

b) Fabrication of the Nanocomposite Scaffold

The scaffold was prepared as per the procedure described in Figure no.2. The quantities of the ingredients in each scaffold are described in Table no.1.

c) Weight Loss

By imbibing the scaffolds in Simulated Body Fluid (SBF), the weight losses of the five scaffold formulations are conceded.

$$\text{Weight Loss (\%)} = [(W_0 - W_t) / W_0] \times 100$$

Where W₀ denotes the weight of the fused scaffold, while W_t is the weight at time (t). The study recurred

thrice, and the mean value is noted. The weight loss data were depicted in Table no.2 and Figure no.3.

d) Swelling Ability

The parched mass of the scaffolds was represented as W_i. Parched scaffolds were submerged in Phosphate Buffer solution at 37°C for 24 hours. Later, the scaffolds were removed from PBS solution, and its damp mass was denoted as W_f. Swelling ability data was depicted in Table no.3.

$$\text{Swelling Ability (\%)} = [(W_f - W_i) / W_i] \times 100$$

e) Porosity Measurement

W_d was used to represent the dry weight of the scaffolds, while W_i designated the mass of the scaffolds after immersing in ethyl alcohol for five minutes. After slight parching over the shallow area, W_w was recorded. The porosity data is described in Table no.4 [12].

$$\text{Porosity (\%)} = (W_w - W_d) / (W_w - W_i) \times 100$$

f) FT-IR Analysis

The spectra of the Chitosan, HPMC, Ofloxacin, and the optimized F5 formulation were documented by means of potassium bromide pellet method in the FT-IR spectrophotometer (JASCO 4100 type A) within the range of 4000cm⁻¹ to 400cm⁻¹ [13].

V. SURFACE ANALYSIS

a) Scanning Electron Microscopy (SEM)

The powdered sample was taken and mounted on a double side carbon tape, which was fixed to sample specimen stub. The SEM (QUANTA FEG) instrument is used for analysis. The SEM images were described in Figure no.4 [14].

b) Optical Microscopy

MOTIC digital microscope is used to image the scaffold at 10X and 40X, as given in Figure no.5.

c) Transmission Electron Microscopy (TEM)

TEM studies were useful in examining the morphological and crystalline arrangements of the scaffold. The principle employed to view the scaffolds is high-resolution transmission electron microscopy (HRTEM). The scaffold's (20 μl) solution was taken. On the carbon-coated side of the copper lattice, the mixture was dripped. At room temperature for few hours, the lattice was dehydrated. The grid was then placed in the sample holder and mounted in the instrument. The instrument TECHNAI T20 was used for the analysis. The TEM images were given in Figure no.6 [15].

d) Electron Dispersive X-Ray Analysis

The elements present in the scaffold were estimated using EDAX analysis. It is given in Figure no.7 [16].

e) X-Ray Diffraction (XRD) Analysis

XRD is employed to determine the crystal-like nature. It was performed with a PAN analytical Xpert Pro X-Ray Diffractometer. The powdered sample for evaluation was taken on the glass slide and placed on the X-Ray diffractometer. The scanning rate was continued over a 2θ range of 10 to 90°. The XRD graph was given in Figure no.8.

VI. IN-VITRO RELEASE STUDIES

100µg of the scaffold was pondered from each of the five formulations primed in different test tubes. To this, pH 7.4 phosphate buffer medium was added and placed in an orbital shaker. The quantity of ofloxacin expelled out from the scaffolds was assessed by amassing buffer medium from the test tubes and supplanting with fresh buffer at 30 minutes' intervals for 5 hours. The amount expelled out was recorded at 294 nm. The discharged amount was ascertained from the standard curve. From this percentage, drug release was calculated, and percentage drug release as plotted versus time. The in-vitro drug release graph was depicted in Figure no.9 [17].

VII. IN-VITRO ANTIBACTERIAL ACTIVITY

a) Agar Disc Diffusion Method

i. Preparation of Inoculum

On agar slant, cultures were conserved at 4°C. By relocating a coil of cells from the cultures to test tubes, lively cultures were developed. The anti-septic action was ascertained by the agar disc diffusion technique.

ii. Antibacterial Activity

The antiseptic activity was ascertained by the well diffusion method on Muller Hinton agar (MHA) medium. MHA was solubilized in purified water, and the medium was sterilized after the addition of agar. Then, the media was transferred into disinfected Petri plates and solidified. By using disinfected swab saturated with the bacterial suspension, the inoculums were spread on the plates. To the wells made, 100,200, 400µg of (F5), 50 µl negative control (HCl), and positive control of streptomycin suspension were added on respective wells. These plates were gestated at 37°C for a day. The area of inhibition was then recorded. The results were depicted in Table no.5 and Figure no.10 [18].

VIII. RESULTS AND DISCUSSION

a) Calibration Curve of Ofloxacin

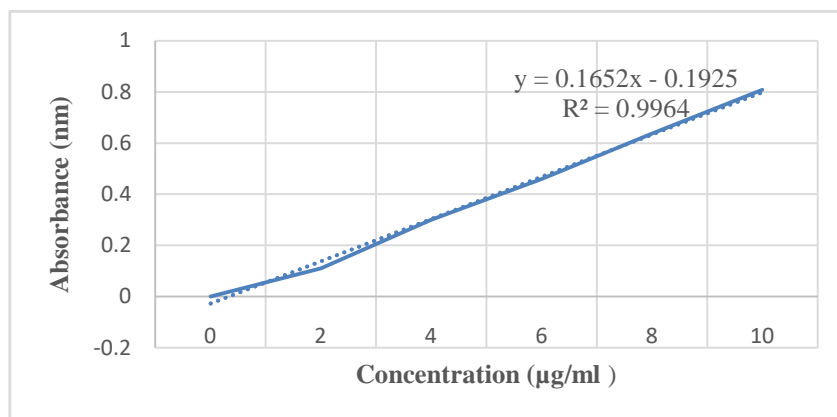


Fig. 1: Calibration curve of Ofloxacin

The calibration curve was found to obey Beers Law in the concentration range of 2-10 µg/ml as given in figure no.1.

b) Fabrication of the Nanocomposite Scaffold

Table 1: Fabrication of Scaffolds

Formulation Code	S1 (mg)	S2 (mg)	S3 (mg)	S4 (mg)
Hydroxyapatite	100	100	100	100
Chitosan	30	30	30	30
SCMC	-	10	-	-
CMC	-	-	10	-
HPMC	-	-	-	10
Ofloxacin	100	100	100	100
2% Acetic Acid	50ml	50ml	50ml	50ml
Water	100ml	100ml	100ml	100ml

Note: Details the composition of S1, S2, S3, and S4 formulations.



Fig. 2: Shows the spongy-like appearance of the scaffold.

c) *Weight Loss*

From the above shown Fig. 3 and Table 3, Scaffold S1 has a maximum weight loss of 8 % during the study. The scaffold S3 showed less weight loss

compared to S2. Scaffold S4 showed the minimum loss of weight (2.7 %) in four weeks and had the less degradation [19].

Table 2: Weight loss data of scaffold formulations

Time (d)	S1 (%)	S2 (%)	S3 (%)	S4 (%)
1	1.5	0.2	0.1	0.0
3	2.7	1.2	0.9	0.0
7	3.9	2.2	1.7	0.5
15	5.4	3.1	2.4	1.2
21	6.9	4.2	3.3	1.9
28	8.0	5.1	4.0	2.7

Note: Represents the loss of weight in % of scaffolds at predetermined time intervals for 28 days.

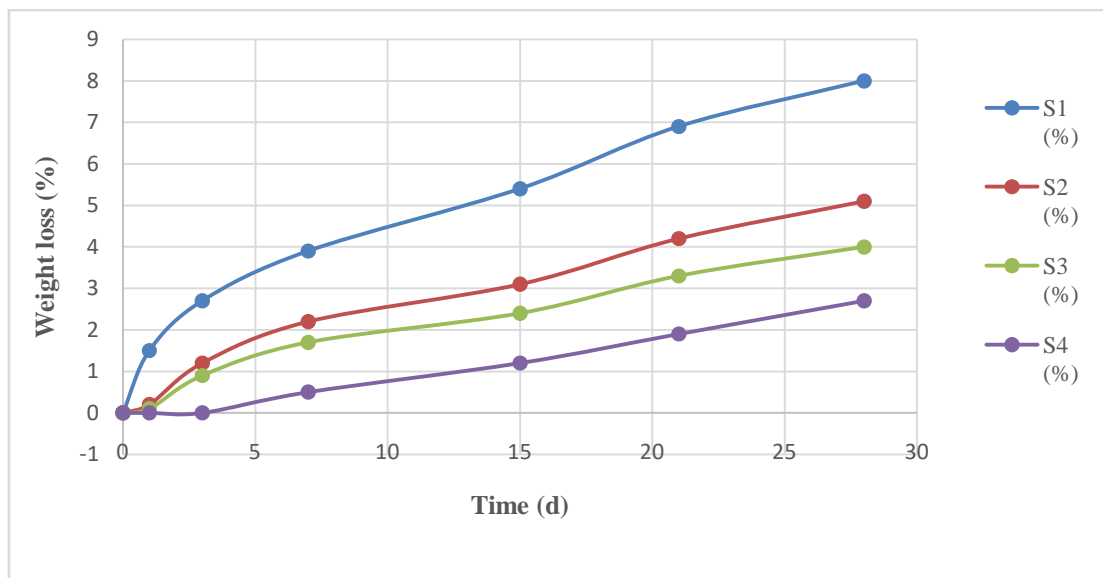


Fig. 3: Weight loss graph of scaffold formulations

From the above results, Scaffold S2 has a maximum weight loss of 8% during the study. The scaffold S4 showed minimum weight loss compared to

S3. Scaffold S5 showed the least loss of weight (2.7%) in four weeks.

d) *Swelling Ability*

The swelling was similar in all the scaffold formulations due to constant hydroxyapatite and chitosan concentrations, as given in table no.3 [20].

Table 3: Swelling ability of scaffold formulations

Formulation Code	W_i (g)	W_f (g)	Swelling Ability (%)
S1	1.00	2.40	140
S2	1.00	2.60	160
S3	1.00	2.50	150
S4	1.00	2.90	190

Table 3 shows the Parched mass (W_i in g), damp mass (W_f in g) and swelling ability (%) of scaffold formulations.

e) *Porosity Measurement*

The porosity of the scaffold formulations was similar to one another, as given in table no.4.

Table 4: Porosity measurement data of scaffold formulations

Formulation Code	W_w (g)	W_d (g)	W_i (g)	Porosity (%)
S1	0.58	0.25	1.15	57.89
S2	0.59	0.25	1.19	56.66
S3	0.62	0.25	1.20	63.79
S4	0.65	0.25	1.24	67.79

Table 4 reveals the parched mass (W_w in g), dry weight (W_d in g), dipped mass (W_i in g) and porosity (%) of the scaffold formulations.

f) *FT-IR Analysis*

The results of the analysis showed various stretching, bending, and rocking vibrations based on the groups present. All the spectra indicated that there are no significant drug-excipient interactions.

IX. SURFACE ANALYSIS

a) *Scanning Electron Microscopy (SEM)*

The images exhibit that the scaffold has an elongated surface which is shown in figure no.4.

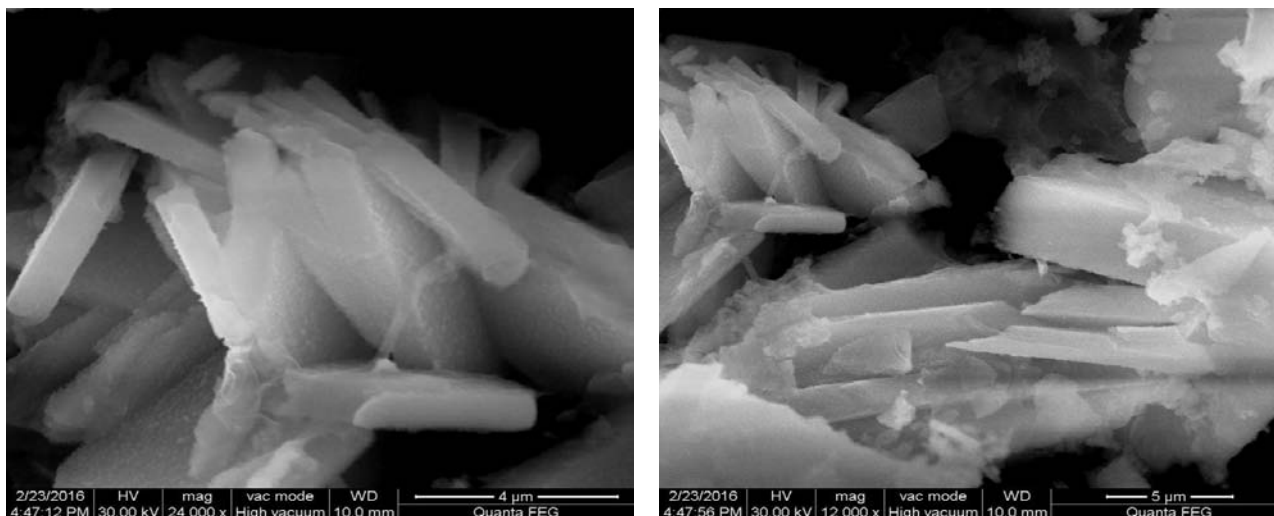


Fig. 4: SEM image

Fig. 4: Portrays the SEM image of the S4 scaffold.

b) *Optical Microscopy*

The images exhibited that the scaffold was found to have a flat structure with smooth surface morphology, as shown in figure no.5.

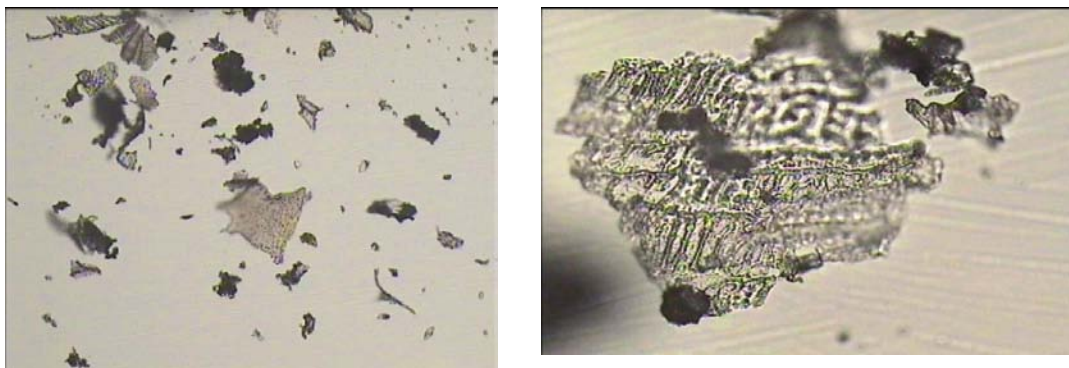


Fig. 5: Image of optical microscopy

Fig. 5 portrays the optical microscopy image of the S4 scaffold where a) 10X image b) 40X image

c) *Transmission Electron Microscopy (TEM)*

TEM report analysis revealed the presence of internal morphology of nanocomposite scaffold with the

sizes of $0.1\mu\text{m}$, $0.2\mu\text{m}$, and $0.5\mu\text{m}$. The internal morphology shows elongated flakes of the scaffold as depicted in Figure no.6 [21].

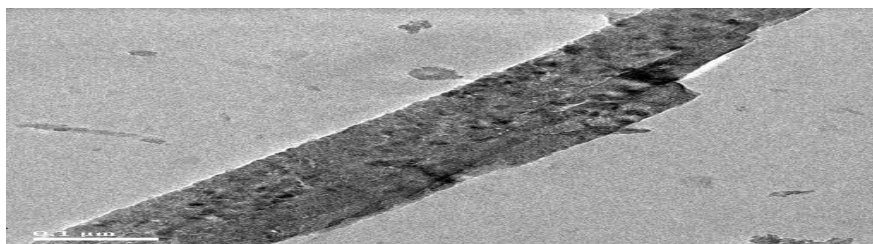


Fig. 6: TEM image

Fig. 6 portrays the TEM image of S4 scaffold.

d) *Energy Dispersive X-Ray Analysis*

The scaffold contains oxygen(O), carbon(C), calcium(Ca), phosphorus(P), magnesium (Mg) and

chlorine(Cl) at 50.80%, 24.93%, 24.64%, 8.19%, 0.50% and 0.36% respectively as shown in Figure no.7 [22].

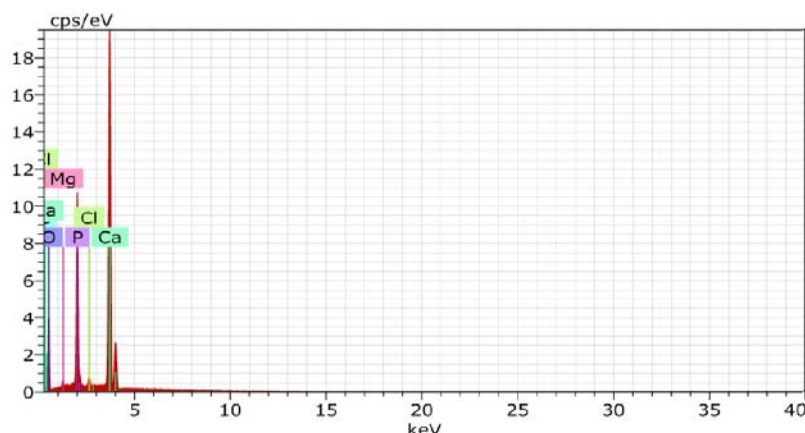


Fig. 7: EDAX analysis

Fig. 7 shows the presence of various elements and their composition of S4 scaffold.

e) *X-Ray Diffraction (XRD) Analysis*

The peaks were obtained at 2θ level at positions 27.21 , 29.15 , 30.65 , 34.35 , 37.03 , 41.61 , 45.44 , 48.45 , 50.42 , 53.60 , 59.59 , 64.05 , and 68.77 .

Hence, the formulated scaffold was found to exhibit the crystalline structure of the scaffold as depicted in figure no.8.

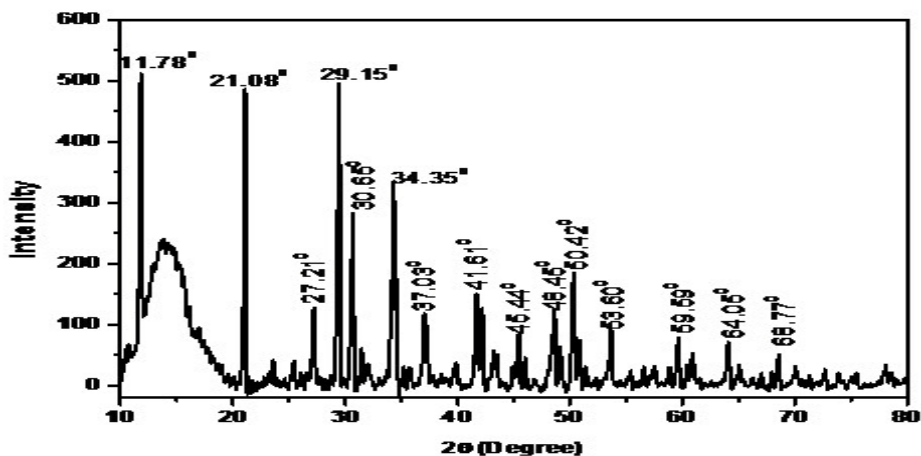


Fig. 8: XRD graph

Fig. 8 shows the 2θ (degree) vs intensity XRD graph of S4 scaffold.

X. IN-VITRO RELEASE STUDIES

From the Figure no.9, the scaffold S4 showed an initial burst release succeeded by a persistent release and the release rate was found to be 100% at the end of 8 hours, whereas scaffolds S2 and S3 showed

release of 62%, and 82% at the end of 8 hours study. However, S5 showed a sustained release profile over an extended period of study of upto 24 hours. Hence, the formulation S5 has been optimized for characterization [23].

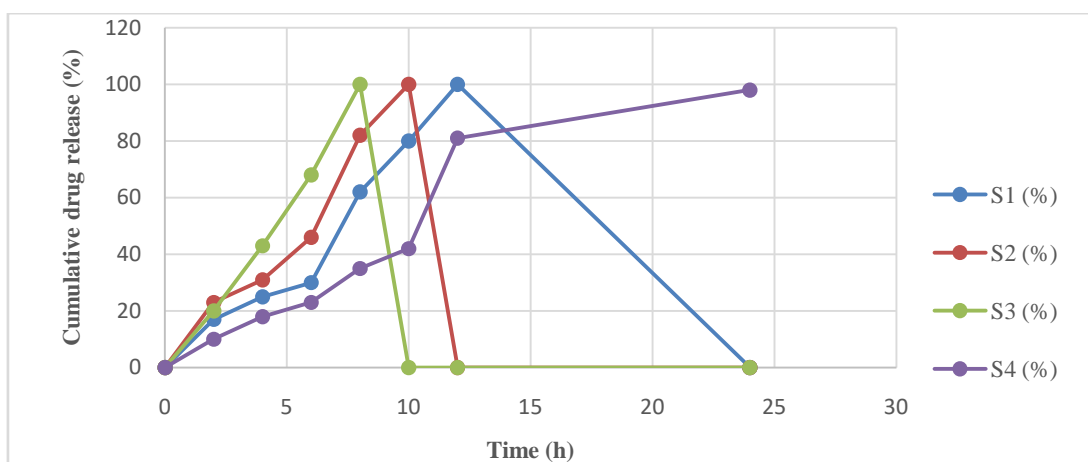


Fig. 9: In-vitro drug discharge profile graph

Fig. 9 shows the time (h) vs. cumulative percentage drug release (%) of the scaffold formulations.

a) In-Vitro Antibacterial Activity

Table 5: In-vitro antiseptic action results

S.No.	Microorganisms	Zone of Inhibition (mm)				
		100 μ g	200 μ g	400 μ g	HCl (negative control)	Streptomycin 15 μ g (positive control)
1	<i>Escherichia coli</i>	26	32	34	23	16

From the report of the antibacterial activity of the formulated scaffold as shown in Table no.5 and Figure no.10, it was found that the scaffold with various concentrations 100 μ g, 200 μ g and 400 μ g when compared with standard positive and negative control, showed maximum zone of inhibition of 26mm, 32mm

and 34mm respectively. Hence the prepared scaffold exhibits antibacterial activity [24].

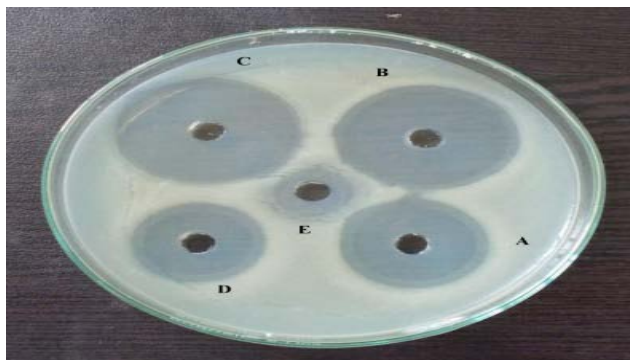


Fig. 10: *In-vitro* antibacterial activity against *E. Coli*

Fig. 10 shows the agar disc plate used for *in-vitro* antibacterial activity where A represents 100 μg of scaffold, B represents 200 μg of scaffold, C represents 400 μg of scaffold, D represents hydrochloric acid (negative control) and E represents standard (positive control).

XI. CONCLUSION

The scaffold is a versatile bioactive product among wound dressing materials, whose production is flexible and economical. The present work was aimed towards fabricating a scaffold containing hydroxyapatite using various polymers like chitosan, carboxy methylcellulose (CMC), sodium carboxy methylcellulose (SCMC), and hydroxypropyl methylcellulose (HPMC) by freeze-drying technique by incorporating Ofloxacin as an anti-microbial agent. Five formulations, namely S1, S2, S3, S4, and S5, were prepared using various combinations of the polymers mentioned. The prepared scaffolds were studied for their characteristic properties like weight loss, swelling ability, porosity, and *in-vitro* drug release studies. The optimized formulation (S5) was characterized by SEM, optical microscopy, TEM, EDAX, XRD, FT-IR, and *in-vitro* antibacterial activity.

Due to the greater water acceptance, sufficient porosity, improved antibacterial activity, and extended drug release, the hydroxyapatite-chitosan-HPMC-ofloxacin scaffold would be a hopeful biomaterial for bone tissue engineering. From this research, it was concluded that the nano-composite scaffold is a viable alternative to existing conventional dosage forms, which lead to improved bioactivity and a promising biomaterial for bone tissue engineering in case of administration affords resulting in better patient compliance and cost-effective therapy in the field of biomedical application.

Conflicts of Interest

Nil

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A Study to Determine the Effect of Egg Albumin Dressing on Peristomal Wound Healing of the Colostomy Patients in a Selected Hospital, Kolkata, West Bengal

By Ms. Rimi Chakraborty, Dr. Arpan Dutta Roy, Dr. Sayantan Ghosh
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Keywords: albumin dressing, peristomal wound healing, colostomy patients, egg albumin.

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Strictly as per the compliance and regulations of:



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A Study to Determine the Effect of Egg Albumin Dressing on Peristomal Wound Healing of the Colostomy Patients in a Selected Hospital, Kolkata, West Bengal

Ms. Rimi Chakraborty ^α, Dr. Arpan Dutta Roy ^σ, Dr. Sayantan Ghosh ^ρ & Dr. Pankaj Kumar Singh ^ω

Abstract- The researcher conducted a quasi experimental study to evaluate the effect of egg albumin dressing on peristomal wound healing in a selected hospital, Kolkata, with the objectives to assess the peristomal skin condition of colostomy patients before treatment, to evaluate the effect of egg albumin dressing on healing of peristomal area and reduction of pain, to find out the association between the peristomal wound healing and selected variables. The final study was conducted at Curzon ward, Victoria ward of SSKM hospital, Kolkata. Ethical permission was sought out from Ethical Committee of SSKM hospital, Kolkata. Informed consent was taken from all respondents. The sample was selected according to their selected criteria. The sample selection was done by purposive sampling. They were randomly assigned into two groups (experimental and control group) in 1:1 ratio. The study concluded with its limitations, implications and recommendations for conducting a study may be conducted for a longer duration of observation with the treatment.

Keywords: albumin dressing, peristomal wound healing, colostomy patients, egg albumin.

I. INTRODUCTION

According to the WHO reports in 2012, cancer is a leading cause of death worldwide, accounting for 8.2 million deaths. Amongst the most common causes of cancer death, about 694000 are from colorectal cancer. Most of the operable colorectal cancers require a surgical procedure called colostomy.

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A colostomy is major surgery that creates an opening (known as a “stoma”) in the colon to permit waste to exit outside the body into a pouch attached to the abdomen. Generally, in a colostomy, part of or the entire colon is removed. A colostomy may be permanent or temporary, depending on the medical condition that has necessitated the surgery. A permanent colostomy is customarily performed when the rectum or most of the colon is removed. ¹

The main purposes of a wound dressing are, to clean the site, absorb exudates, if any, ease pain and provide protection from infection. The wound dressing should ideally fulfill some primary and secondary requirements. ²

The primary requirements would be that the dressing is free of toxic or irritant extractable, should not release particles or non-biodegradable fibres into the wound, should form an effective bacterial barrier, forms an effective water-resistant seal to the periwound skin, but is easily removable without causing trauma or skin stripping should be able to maintain the wound and the surrounding skin in an optimum state of hydration, provide protection to the periwound skin from potentially irritant wound exudates and excess moisture, produce minimal pain during application or removal as a result of adherence to the wound surface and maintain the wound at the optimum temperature and pH. The secondary requirements should include antimicrobial activity, ability to remove or inactivate proteolytic enzymes in chronic wound fluid, possess haemostatic activity and have effective wound debriding activity. ³

II. NEED OF THE STUDY

One of the main types of stoma is colostomy, which has a risk of forming sore on the peristomal skin. Through the stomas, feces and body fluid are collected in the stoma appliance. The stoma appliance is attached to the peristomal skin with adhesive. As there is a chance of continuous seepage of feces and body fluid through this stoma there is a high chance of skin excoriation at peristomal region due to the corrosiveness of that feces and body fluid. Also the continuous pressure and friction caused due to the

adhesive of the stoma appliance contribute to the chances of excoriation of the peristomal skin. The severity of the excoriation depends primarily on these factors. It is essential to ensure that the skin surface, on which the appliance is attached, is free from breaks or soreness as this might lead to appliance leakage.

Generally enterostomal therapist takes care of these stomas in the post operative period. As there is an inadequate number of enterostomal therapist, the general nurse also has a vital role to take care of the patient with a stoma. Taking care of the patient with any ostomy is indeed a challenge to any nurse.

The investigator during her clinical experience noticed that the peristomal skin excoriation is very common in the patient having colostomy and different types of dressing, commercially available in the market viz, ostomy powder, ostomy paste, hydrocolloid based appliances, etc are applied to reduce peristomal skin complications. The investigator, considering the increasing number of cases from different economic backgrounds, has felt that there is a need to look into alternative dressing materials.

Use of egg white for treatment and healing of wounds was an old Roman technique for treating gunshot wounds. Egg white constitutes about 20-25% of the egg. The egg white is composed of proteins and minerals. Different types of proteins are present in egg white.

Some of them are Ovalbumin, Conalbumin, Ovamucoid, Ovomucin, Lysozyme, Avidin, Ovoglobulin, Ovoinhibitor. It also contains minerals like Sulphur, which has antibacterial and anti-inflammatory properties and Copper which is toxic to bacteria and also used in a number of rejuvenating and skin revitalizing treatments. These properties of egg albumin make it suitable to be used in topical application in medical dressing.

Thus the investigator thought that topical application of egg white dressing may be an effective healing agent for peristomal wounds.

III. OBJECTIVES

- To evaluate the effect of egg albumin dressing on healing of the peristomal skin area and reduction of pain among experimental group of colostomy patients.
- To assess the peristomal skin condition among experimental group of colostomy patients before treatment.
- To assess the peristomal skin condition among control group of colostomy patients before treatment.
- To find out the association between the peristomal wound healing and selected sample characteristics.

IV. STUDY CRITERIA

a) Inclusion Criteria

- Colostomy patients admitted in the surgical ward on their 5th postoperative day onward
- Patients who are willing to participate in the study
- Adult patient >18years of age irrespective of their disease condition.

b) Exclusion Criteria

- Known allergic condition to egg albumin

V. MATERIALS & METHOD

Study Type:

The Study was a Quasi experimental research approach.

Study Design:

The design adopted for this study is pre-test post-test control group time series design.

Operational Definitions:

Colostomy Patient: In this study, colostomy patient refers to patients more than 18 years age, admitted in the surgical ward of the selected hospital on the 4th postoperative day of permanent or temporary colostomy.

Peristomal skin: It refers to the area surrounding the stoma where appliance is attached.

Egg albumin dressing: It refers to the direct application of the raw egg white portion with the help of sterile gauge piece, once in a day, on alternate days, for a total of three times, on the peristomal skin, after cleaning the region with 0.9% normal saline

Effect: It refers to whether the desired effect of egg albumin dressing has achieved or not and is measured by healing score.

Peristomal skin wound: Peristomal skin wound is assessed by modified Ostomy Skin Tool, the wound status is assessed through rating scale and will be measured by DET Scoring in terms of the discoloration, erosion, and tissue overgrowth.

Table 1: Schematic representation of data collection instruments

Tool No	Name of the tool	Variables to be measured	Technique
Tool-I	Semi-structured interview schedule	Demographic profile	Interview
Tool-II	Health assessment proforma Record analysis proforma	Height, weight, BMI Illness profile	Measurement Record analysis
Tool-III	Modified Ostomy Skin Tool	Peristomal skin wound status	Assessment
Toll-IV	Visual analogue scale	Wound pain	Assessment

Selected sample characteristics: Selected sample characteristics will include demographic profile (consist of age, sex, education, occupation, income), health assessment (height, weight BMI), illness profile (duration of illness, time taken to diagnose, duration of peristomal skin wound, cancer stage, nature of surgery, no of postoperative days in intensive care unit, presence of Diabetes mellitus, hypertension, feeding pattern, blood report of HB%, WBC, ESR).

Data Collection Procedure:

The final study was conducted at Curzon ward, Victoria ward of SSKM hospital. Kolkata.

Ethical permission was sought out from Ethical Committee of SSKM hospital, Kolkata. Informed consent was taken from all respondents. The sample was selected according to their selected criteria. The sample selection was done by purposive sampling .But randomly assigned into two groups (experimental and control group) in 1:1 ratio. First one was selected as experimental group and second one as control group. In this way 15 patients in the experimental group were

selected and coded as E1, E2, E3, E15 and another 15 patients in the control group were selected and coded as C1, C2, C3 C15.

The Data was Analysed-using

Section I- The findings related to the description of the demographic characteristics of the colostomy patients presented in frequencies and percentage distribution.

Section II A- The findings related to the description of the health assessment of the colostomy patients presented in frequencies and percentage distribution.

Section II B- The findings related to the description of the illness profile of the colostomy patients presented in frequencies and percentage distribution.

Section III- The findings related to the pre intervention score of experimental group and control group by mean, median, and standard deviation.

Study Site

The study was conducted at the surgical ward of the SSKM Hospital, Kolkata.

VI. RESULTS

Table 2: Frequency and percentage distribution of the colostomy patients according to their age, sex and educational qualification

n = 30 (15+15)

Sample Characteristics	Experimental Group		Control Group	
	Frequency (f)	Percentage (%)	Frequency (f)	Percentage (%)
Age (In years)				
18-30	1	6.7	1	6.7
31-50	10	66.7	11	73.3
51-70	4	26.7	3	20
Sex				
Male	8	53.3	10	66.7
Female	7	46.7	5	33.3
Educational Qualification				
Primary	8	53.3	9	60.0
Secondary	5	33.3	3	20.0
Higher Secondary & Above	2	13.3	3	20.0

Table 3: Frequency and percentage distribution of the colostomy patients according to their occupation, monthly family income and diagnosis

n = 30 (15+15)

Sample Characteristics	Experimental Group		Control Group	
	Frequency (f)	Percentage (%)	Frequency (f)	Percentage (%)
Occupation				
Service	2	13.3	3	20
Daily labor	5	33.3	4	26.7
Business	8	53.3	8	53.3
Monthly Family Income				
< 4000/-	Nil	-	1	6.7
4000/- and above	15	100	14	93.3
Diagnosis				
CA Rectum	7	46.7	6	40
CA Colon	8	53.3	9	60

Section-II A Finding related to the description of the health assessment of the colostomy patients

Table 4: Frequency and percentage distribution of colostomy patients according to their height, weight and BMI

Sample Characteristics	Experimental Group		Control Group	
	Frequency (f)	Percentage (%)	Frequency (f)	Percentage (%)
Height in cms				
>137-150	6	40	7	46.7
>150-163	7	46.7	6	40
>163-176	2	13.3	2	13.3
Weight in kg				
40-45	4	26.7	5	33.3
45-50	7	46.7	5	33.3
50-55	3	20	3	20
55-60	Nil	-	1	6.6
60-65	1	6.6	1	6.6
BMI				
Normal	10	66.7	9	60
Low	5	33.3	6	40

Table 5: Frequency and percentage distribution of colostomy patients according to their cancer stage, type of surgery performed and no of days stay in ICU

Sample Characteristics	Experimental Group		Control Group	
	Frequency (f)	Percentage (%)	Frequency (f)	Percentage (%)
Cancer stage				
Stage-I	5	33.3	6	40
Stage-II	6	40	6	40
Stage-III	4	26.7	3	20
Types of surgery performed				
Therapeutic	15	100	15	100
Palliative	Nil	-	Nil	-

No of days stay in ICU				
2 Day	Nil	-	2	13.3
3 Day	Nil	-	Nil	-
None	15	100	13	86.7

Table 6: Frequency and percentage distribution of colostomy patients according to the presence of diabetes mellitus, hypertension and haemoglobin levels

Sample Characteristics	Experimental Group		Control Group	
	Frequency (f)	Percentage (%)	Frequency (f)	Percentage (%)
Diabetes mellitus				
Absent	11	73.3	9	60
Present	4	26.6	6	40
Hypertension				
Absent	15	100	12	80
Present	Nil	-	3	20
Hb level				
Normal	7	46.7	6	40
Below normal	8	53.3	9	60

Table 7: Frequency and percentage distribution of colostomy patients according to their WBC count, ESR level and mode of feeding

Sample characteristics	Experimental Group		Control Group	
	Frequency (f)	Percentage (%)	Frequency (f)	Percentage (%)
White blood cell count				
Above normal	4	26.7	7	46.7
Normal	11	73.3	8	53.3
ESR level				
Above normal	Nil	-	Nil	-
Normal	15	100	15	100
Mode of feeding				
Enteral	15	100	15	100
Parental	Nil	-	Nil	-

Section-III Findings related to the pre intervention peristomal skin wound score of experimental group and control group by mean, mean difference and standard deviation.

Table 8: Mean, Mean Difference and Standard Deviation of pre-intervention score of experimental and control group of colostomy patients

Group	Domain	Mean	Mean D	SD
Experimental	Discoloration	4.06	0	0.99
Control		4.06		0.99
Experimental	Erosion	3.80	0.07	0.97
Control		3.73		0.98
Experimental	Tissue overgrowth	2.26	0.07	0.92
Control		2.33		0.93

Section-IV Finding related to the distribution of the colostomy patients according to the preobservation pain score observed by VAS

Table 9: Frequency and percentage distribution of colostomy patients according to the preintervention pain score observed by VAS

Degree of Pain	Experimental Group		Control Group	
	Frequency (f)	Percentage (%)	Frequency (f)	Percentage (%)
Little Discomfort (1-2)	1	6.7	1	6.7
Mild Pain (3-4)	5	33.3	5	33.3
Moderate Pain (5-6)	8	53.3	7	46.7
Severe pain (7-8)	1	6.7	2	13.3

Section V Effectiveness of egg albumin dressing for Peristomal skin wound healing.

There is a significant difference of mean score of peristomal skin wound discoloration in colostomy patients in experimental group before and after application of egg albumin dressing as measured by modified ostomy skin tool at 0.05 level of significance.

Table 10: Mean, Mean Difference, SD, SE and Paired "t" value of pre and post intervention colostomy skin wound discoloration score by modified Ostomy Skin Tool in experimental Group n = 15

Observation	Mean	MD	SD	SE	't'
Before treatment	4.06	2.06	0.99	0.42	4.84*
After treatment	2.00		1.31		

$df (14) = 2.15, p < 0.05$

There is a significant difference of mean score of peristomal skin wound erosion in colostomy patients in experimental group before and after application of egg albumin dressing as measured by modified Ostomy Skin Tool at 0.05 level of significance.

Table 11: Mean, Mean Difference, SD, SE and Paired "t" value of pre and post intervention colostomy skin wound erosion score by modified Ostomy Skin Tool in experimental n = 15

Observation	Mean	MD	SD	SE	't'
Before treatment	3.8	2.00	0.97	0.42	4.69*
After treatment	1.8		1.32		

$df (14) = 2.15, P < 0.05$

There is a significant difference of mean score of peristomal skin wound tissue overgrowth in colostomy patients in experimental group before and after application of egg albumin dressing as measured by modified Ostomy Skin Tool at 0.05 level of significance.

Table 12: Mean, Mean Difference, SD, SE and Paired "t" value of pre and post intervention colostomy skin wound tissue overgrowth score by modified Ostomy Skin Tool in experimental Group

Observation	Mean	MD	SD	SE	't'
Before treatment	2.26	1.66	0.92	0.28	5.80*
After treatment	0.6		0.61		

$df (14) = 2.15, p < 0.05$

There is a significant difference of mean post intervention score of Peristomal skin wound discoloration in colostomy patients in the experimental group getting egg albumin dressing than that of control group assumed to get conventional treatment at 0.05 level of significance.

Table 13: Mean, Mean Difference, SD, SE and Unpaired “t” value of experimental and control group post observation score of discoloration measured by Modified Ostomy Skin Tool

Group	Mean	MD	SD	SE	‘t’
Experimental Group	2.0	-2.0	1.31	0.42	4.74*
Control Group	4.0		0.96		

df (28) = 2.05, p < 0.05

There is a significant difference of mean post intervention score of peristomal skin wound erosion among colostomy patients in the experimental group getting egg albumin dressing than that of control group assumed to get conventional treatment at 0.05 level of significance.

Table 14: Mean, Mean Difference, SD and Unpaired “t” value of experimental and control group post observation score of erosion measured by modified Ostomy Skin n=30(15+15)

Variable	Mean	MD	SD	SE	‘t’
Experimental Group	1.8	-1.8	1.32	0.43	4.16*
Control Group	3.6		1.01		

df (28) = 2.05, p < 0.05

There is a significant difference of mean post intervention score of Peristomal skin wound tissue overgrowth among colostomy patients in the experimental group getting egg albumin dressing than that of control group assumed to get conventional treatment at 0.05 level of significance.

Table 15: Mean, Mean Difference, SD and Unpaired “t” value of experimental and control group post observation score of tissue overgrowth measured by modified Ostomy Skin n = 30 (15+15)

Variable	Mean	MD	SD	SE	‘t’
Experimental Group	0.6	-1.4	0.61	0.26	5.31*
Control Group	2.00		0.81		

df (28) = 2.05, p < 0.05

application of egg albumin dressing as measured by VAS at 0.05 levels of significance.

Section VI: Effectiveness of egg albumin dressing for reducing degree of Peristomal skin wound pain.

There is a significant difference of mean Peristomal skin wound pain score among colostomy patients in experimental group before and after

There is a significant difference of mean Peristomal skin wound pain score among colostomy patients in experimental group before and after application of egg albumin dressing as measured by VAS at 0.05 levels of significance.

Table 16: Mean, Mean Difference, SD and Paired “t” value of pre and post Intervention peristomal skin wound pain score by VAS in experimental Group n = 15

Observation	Mean	MD	SD	SE	‘t’
Before treatment	5.2	4.0	1.42	0.48	8.25*
After treatment	1.2		1.22		

df (14) = 2.15, P < 0.05

the experimental group getting egg albumin dressing than that of control group assumed to get conventional treatment at 0.05 levels of significance.

There is a significant difference of mean post intervention score Of pain among colostomy patients in the experimental group getting egg albumin dressing than that of control group assumed to get conventional treatment at 0.05 levels of significance.

There is a significant difference of mean post intervention score of pain among colostomy patients in

Table 17: Mean, Mean Difference, SD, SE and Unpaired “t” value of experimental and control group wound pain score measured by VAS
n=30

Group	Mean	MD	SD	SE	t'
Experimental	1.2	-2.8	1.22	0.45	6.16*
Control	4.0		1.26		

df (28) = 2.05, P < 0.05

Section-VII Findings related to the association between peristomal skin wound healing and illness profile of the colostomy patients.

Table 18: Chi-square to find out the association between selected sample characteristics and Peristomal skin wound
n = 15

Sample characteristics	Post observation score		x2 value
	< Median	≥ Median	
BMI			
Normal	8	2	2.8
Below normal	1	4	
Diabetic Mellitus			
Present	2	2	1.03
Absent	1	10	
Haemoglobin Level			
Below normal	3	5	1.87
Normal	6	1	
WBC Count			
Above normal	1	3	1.83
Normal	10	1	

$$\chi^2 (1) = 3.84, p < 0.05.$$

helped in effective sealing between the stoma appliance and the peristomal skin.

The present study has also revealed that healing of the peristomal skin wound was achieved by the application of egg albumin dressing in terms of tissue overgrowth, discolouration, and controlling tissue erosion. This is line with the reports published by Zou, C, Kobayshi, K and Kato (1991) who had observed the morphological changes in some cell types under the influence of egg white, suggesting that egg white may promote cell differentiation.

VII. DISCUSSION AND CONCLUSION

The present study was likely to be supported by the study of Parkinson, 1999, who conducted a study and evaluated that the major proteins of albumen are ovalbumin, conalbumin (ovotransferrin), ovomucoid, lysozyme and ovomucin. Lysozyme which forms a chemical protection against microorganism, by dissolving the cell wall of bacteria, constitutes about 3.5% of the egg. This prompted the researcher to conduct this study with a desire to study the effect of application of egg albumin, in peristomal wound dressing, with respect to its healing of the wound.

The present study has revealed that satisfactory healing of the peristomal skin wound was achieved by the application of egg albumin dressing in terms of reduction of irritation in the wound area. Similar reports have been published in the study to determine the effect of cyanoacrylate protectant to manage peristomal skin irritation under ostomy skin barrier wafers conducted by Catherine T. Milne, Darlene Saucier, ChenelTrevellini, Juliet Smith (2010). Additionally, their study also reported the adhesive properties of egg albumin which

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A Detailed Review on Plant Material used in Hair Growth or in Alopecia

By Chaurasiya Raunakkumar, Jayalalita Kamble & Usha Verma

Abstract- Alopecia areata is a condition that causes hair to fall out in tiny patches, which may be unnoticeable. These patches will however, bind and then become noticeable. The disease develops when the immune system attacks the hair follicles, which results in hair loss. In the form of solitary or multiple patches of alopecia, the most prominent site affected is the scalp. Alopecia areata occurs in males and females of all ages, but in infancy there is always an onset. At some stage in their lives, over 147 million people worldwide have, had or may develop alopecia areata. Some important classes of Alopecia were involved by Alopecia areata, Moderate Transient AA, Transient AA, Alopecia Totalis, Ophiasis AA, Alopecia Universalis. Genetic predisposition, autoimmunity, and environmental factors play a major role in the etiopathogenesis of AA. Corticosteroids are the most popular drugs for the treatment of this disease. Marigolds (*Calendula officinalis*) contain triterpenoid esters, flavoxanthin and auroxanthin carotenoids. Most leaves contain lutein (80%), zeaxanthin (5%) and beta-carotene.

Keywords: alopecia areata, hair care formulation, percentage yield, medicinal plants.

GJMR-B Classification: NLMC Code: QV 704, WR 460



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A Detailed Review on Plant Material used in Hair Growth or in Alopecia

Chaurasiya Raunakkumar ^α, Jayalalita Kamble ^σ & Usha Verma ^ρ

Abstract- Alopecia areata is a condition that causes hair to fall out in tiny patches, which may be unnoticeable. These patches will however, bind and then become noticeable. The disease develops when the immune system attacks the hair follicles, which results in hair loss. In the form of solitary or multiple patches of alopecia, the most prominent site affected is the scalp. Alopecia areata occurs in males and females of all ages, but in infancy there is always an onset. At some stage in their lives, over 147 million people worldwide have, had or may develop alopecia areata. Some important classes of Alopecia were involved by Alopecia areata, Moderate Transient AA, Transient AA, Alopecia Totalis, Ophiasis AA, Alopecia Universalis. Genetic predisposition, autoimmunity, and environmental factors play a major role in the etiopathogenesis of AA. Corticosteroids are the most popular drugs for the treatment of this disease. Marrigolds (*Calendula officinalis*) contain triterpenoid esters, flavoxanthin and auroxanthin carotenoids. Most leaves contain lutein (80%), zeaxanthin (5%) and beta-carotene. Flavonol glycosides, triterpene oligoglycosides, oleanane-type triterpene glycosides, saponins, sesquiterpene glucosides are present in *C. officinalis* flowers and the flowers, which produce 29.8mg/100g, are a rich source of lutein. The Withanolides-which are triteroene lactones-with anolides, withaferin A, alkaloids, steroidal lactones and cuscohygrine are the principal phytochemical constituents of Ashwagandha (*Withaniasamniifera*).

Keywords: alopecia areata, hair care formulation, percentage yield, medicinal plants.

I. INTRODUCTION

Alopecia is a condition in which patchy, confluent or diffuse sample hair loss happens from special regions of the frame, usually from the scalp.¹ In 1

2% of cases, the condition may additionally unfold to the complete scalp or epidermis known as either alopecia total is or alopecia universal is, respectively. occurrence of alopecia is approximately zero.1–zero.2% with entire life chance of men and women similarly.² some sufferer loss all the hair from their heads (Alopecia total is)³ or all frame hairs (Alopecia universal is).⁴ AA is a non-scaring kind of Alopecia.⁵ It's miles one of the maximum common place shape of hair loss visible through dermatologists and debts for 25% of all the alopecia case.⁶ It turned into first described with the aid of Cornelius Celsus, and the term AA become coined by Sauvagein1760.⁷ It accounts for 2-3% of the new dermatology instances in United Kingdom and Americas, three.eights% in China, and 0.7% in India.^{7,8} In popular population, the prevalence become anticipated at 0.1-zero.2% with a lifetime threat of 1.7%.⁸It is able to arise at any age. The youngest become four-months-antique, and the oldest turned into in late seventies.⁹ Twenty percent of cases have been kids, and 60% of AA patients had their first patch earlier than twenty years of age.¹⁰ Highest incidence changed into between 30-fifty nine yrs of age.¹ family contributors are affected in eight.7-20% of instance.^{7,9}



Figure 1: Localized patch of AA



Figure 2: Ophiasis

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a) *Marigold (Calendula)*¹¹: (*Asteraceae*)

• Part Used- Flowers

It is a family of Asteraceae of herbaceous annual and perennial plants, sometimes referred to as marigold.^{12,13} It is used because of its nematocidal, cosmetic and pharmaceutical properties. Antioxidants

are present in the essential oil of the flower.¹⁴ Calendula is used topically to treat acne, minimize inflammation, control bleeding, and soothe irritated tissue in suspension or in tincture.¹⁵ Some bacteria provide growth-promoting substances to plants and play an important role in phosphate solubilization.³²



Figure 3: Marigold

b) *Ashwagandha (Withaniasomnifera)*: (*Salonaceae*)

• Part Used- Roots

It is also commonly planted in the Saloniaceae or nightshade family as winter cherry.^{16,17} It aids in the fight against free radicals in the scalp and hair follicles, promoting healthy hair development. Multiple other species are morphologically similar in the genus withania.¹⁷ It is commonly used in the treatment of various illnesses, such as asthma, bronchitis, inflammatory disorders, ulcers, issues with the stomach.¹⁸ Several studies have shown that ashwagandha is a very effective solution to treating neurological conditions such as Parkinson's and Alzheimer's.¹⁹



Figure 4: Withaniasomnifera

c) *Emblica officinalis (Amla)*: (*Euphorbiaceae*)

• Part used-Fruit

It is one of the most commonly used herbs in Indian homes and indigenous medicine texts.²⁰ In traditional medicine, Emblica is used to stimulate hair growth. The fruits contain tannins as well as antioxidants Emblicanin A and B, and when hydrolyzed, one yields gallic acid, ellagic acid, and glucose, while the other yields only ellagic acid and glucose.²¹ Emblica is said to help with iron metabolism. It is necessary for normal hair growth and good hair care.²²



Figure 5: Amla

d) *Acacia concinna (Shikakai)*: (*Mimosaceae*)

• Part Used- Leaves and Pods

Commercially, *Acacia concinna* is grown in India and Far East Asia. Spinasterol, acacic acid, lactone, and the natural sugars glucose, arabinose, and rhamnose are all produced when the shikakai plant is hydrolyzed. Shikakai can reinforce your hair strands and reduce hair fall if you use it on a daily basis. It is high in Vitamin C, as well as Vitamins A, D, E, K, and other antioxidants, all of which are essential for healthy and rapid hair growth.^{23,24}



Figure 6: Shikakai

e) *Polygonum multiflorum* (*Fallopia multiflora*): (*Polygonaceae*)

- Part Used- Roots

It is a well-known traditional Chinese herbal medicine that is widely spread in northeast Asia. It is also used to prevent kidney and liver ageing, nourish the blood, strengthen and stabilise the lower back and knees, and fortify the muscles, tendons, and bones.^{25,26} P. multiflorum roots have also been shown to have hair growth activity in traditional medicine, and several studies have shown that they have a significant impact on hair growth and colour.²⁷



Figure 7: Fallopia multiflora

f) *Centella asiatica* (*Brahmi booty*): (*Alpiaceae*)

- Part used-Leaves

Centella asiatica is a fragrant, small plant native to India. Asiatic and brahmic acids are found in Brahmi booty. It is also widely used in the treatment of alopecia. It serves as a make a sign for hair growth. It is extremely important for strengthening hair follicles and nourishing the scalp. *Centella asiatica* leaves are used to treat bacterial, viral, and parasitic infections like urinary tract infection, leprosy, cholera, dysentery, syphilis, the common cold, influenza, and tuberculosis.²⁸



Figure 8: Brahmi booty

g) *Zizyphus jujube*(*Jujuba*): (*Rhamnaceae*)

- Part Used- Seeds

It is widely disseminated in Europe and Southeast Asia. Its fruits are edible, and various sections have medicinal properties such as antifertility, analgesic, and diabetes prevention.^{29,30} The essential oil of

Zizyphus jujuba also has a hair-growth-promoting effect. Z. jujuba seeds have been used to treat anti-insomnia and anxiety.³¹



Figure 9: Jujuba

Botanical Name	Family	Medicinal Part
Marrigold	Asteraceae	Flower
Ashwagandha	Salonaceae	Root
Emblcaofficinna	Euphorbiaceae	Fruit
Acacia concinna	Mimosaceae	Leaves & Pods
Polygonum multiflorum	Polygonaceae	Roots
Centella asiatica	Alpiaceae	Leaves
Zizyphus jujube	Rhamnaceae	Seeds

II. CONCLUSION

Alopecia areata has a major effect on the appearance and mental health of those who are affected. The current project focuses on various plants that people use to treat dermatological conditions and hair care. Ashwagandha helps to encourage healthy hair growth by stimulating the development of DHEA, a natural hormone in your body that is an ultimate antioxidant. Amla's phytonutrients, vitamins, and minerals help to boost scalp circulation and promote healthy hair growth. Ayurvedic medicine uses Brahmi, a creeping herb. It contains alkaloids that are thought to activate hair-growth proteins. The essential oil of jujuba has a hair-growth-promoting effect.

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DNA Looping Initiating Types of Machinery of Transcription, Recombination, and Replication: An Experimental, and Theoretical Insight

By Rajiv Kumar & Mitrabasu Chhillar

Opinion- Topological DNA assemblies governed biological processes, physical manipulations, compartmentalization, transfer genetic information by sequence, participates in molecular mechanisms of formation and deformation of biological processes, and even chromosome territory formation, including replication, transcription, and gene regulation via dynamic assets and variations.[1] The sequencing processes deal with DNA mechanical code and leave impacts on gene regulation via nucleosome positioning. Therefore, a proper analysis could predict the mechanical route of DNA sequencing and how it does influence loop creation. The earlier mentioned predictions testified via in-vivo transcription and in-vitro single-molecule assays. These styles of elucidation based on theoretical investigations of various cellular routes of biological processes such as sequence-dependent features of DNA, a specific sequence creation in the chromatin structure, and interfaces of protein and DNA molecules.

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DNA Looping Initiating Types of Machinery of Transcription, Recombination, and Replication: An Experimental, and Theoretical Insight

Rajiv Kumar ^α & Mitrabasu Chhillar ^σ

OPINION

Topological DNA assemblies governed biological processes, physical manipulations, compartmentalization, transfer genetic information by sequence, participates in molecular mechanisms of formation and deformation of biological processes, and even chromosome territory formation, including replication, transcription, and gene regulation via dynamic assets and variations.[1] The sequencing processes deal with DNA mechanical code and leave impacts on gene regulation via nucleosome positioning. Therefore, a proper analysis could predict the mechanical route of DNA sequencing and how it does influence loop creation. The earlier mentioned predictions testified via in-vivo transcription and in-vitro single-molecule assays. These styles of elucidation based on theoretical investigations of various cellular routes of biological processes such as sequence-dependent features of DNA, a specific sequence creation in the chromatin structure, and interfaces of protein and DNA molecules. As referred before, the nonspecific protein-DNA interactions are a significant feature of dynamics paths involved in DNA loop formations.[2] Alternatively, to have a proper understanding of interactions and conformational dynamics, a more scientific analysis of molecular simulations will defiantly offer experimental and theoretical insight. The phenomenon of DNA looping participates in biological processes, including transcription, recombination, and replication, as well as gene regulation, recombination, and chromosomal activities. The structural features and physical interactions of proteins are the strategic factors associated with DNA looping.[3] These biophysical individualities can change the length scale transforms during looping. Changes in the conformation and mechanical deformation of the DNA initiate thermal fluctuations and govern the thermodynamics by generating entropy to influence looping and unlooping processes.

A theoretical model was prescribed, which explained the protein interactions, DNA mechanics, and conformational entropy-defined DNA looping and unlooping, and reply unanswered queries such a show this phenomenon does affect it. These insights proved that DNA deformation and entropy affect the kinetics of the looping and unlooping process.[4] Deformability, bendability, and variability of the DNA chain tempers the kinetics and disturb the interaction. The biophysical and thermodynamics change aloofness in earlier scale predictions. These perturbations and conformational changes manipulate genetic information. An experimental and theoretical insight dreadfully appropriate for the systematic quantitative divisions, and further, it answers back the queries, such as how DNA sequence does disturb looping at such a scale. Few transcription factors such as concentration, length, and sequence influence the phenomenon of DNA looping. These changes can be calculated experimentally and theoretically for better insight into the distinctions between mechanics of nucleosome formation and looping in the short length scale (figure 1).[5] These derived mechanisms of DNA-looping are too important for different types of machinery of networks of DNA metabolism, including transcription, recombination, and replication.

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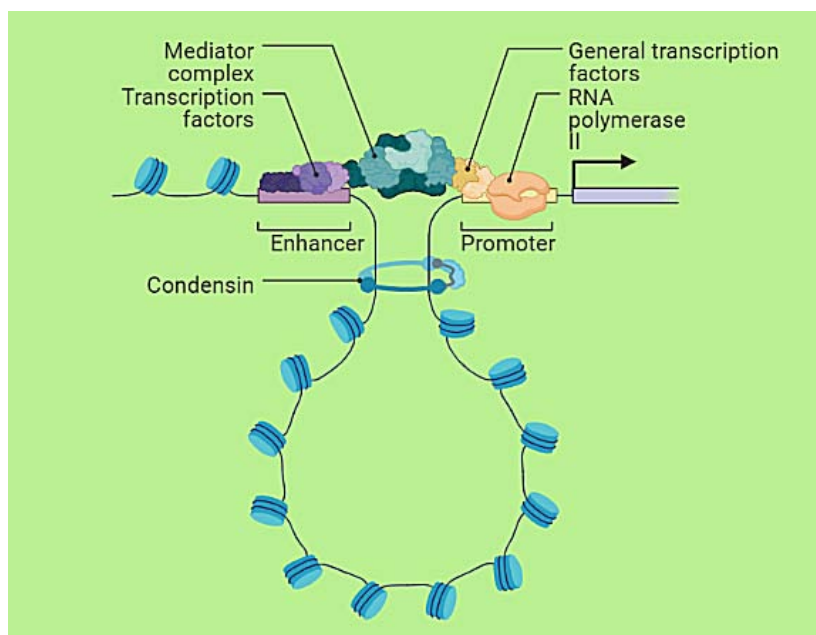


Fig. 1: Diagram for illustrating the DNA looping in the regulation of transcription, physical constraints and macromolecular complexes. “Acknowledged [biorender.com] for permission to adapt and create the figure”.

The routes of replication and transcription types of machinery are too complicated, and therefore a better elucidation of these mechanics can expose genomic instability by providing a better clarification of transcription-replication collision mechanisms. The experimental and theoretical analyses of these biological and biophysical processes help specify the encounters that set off via transcription-replication and support co-orientation of replication and transcription.[6] These discoveries are pathfinder and a source of scientific events that show directions on how to avoid or resolve transcription-replication collisions, for example, alterations in DNA supercoiling hindering replication or chromatin-remodeling complexes. Transcription-replication and DNA damage intertwined at the collisions. At once, some types of machinery of transcription-DNA replication encounter each other at regular intervals and originate genome instability to promote diseases.[7] Several factors and mechanisms exist in cellular types of machinery for inhibiting, blocking, or resolving these unusual events of cell physiology.

Further, the transcription backings mitotic recombination that will have replicate fork progression, provoking its evading and breaking.[8] In simple words, this phenomenon can address as cross-talk between transcription and recombination, in which originated conflict initiates recombinogenic DNA breaking and cotranscriptional R-loops formed.[6] One of the authors, (MB) identified the aforesaid occurrence as one of the major causes of DNA genetic reshuffling. Further, he stressed that these newly originated interfering events occurred between transcription and replication. A few queries emerged from it, such as “does it have similarities with the route of genome dynamics

influenced by RNA.” In this opinion, some other similar emerging questions and outlooks are discussed based on the interference between transcription and replication, as well as the way RNA influences genome dynamics. Another author (RK) pointed out G-quadruplexes that governed transcription, translation, and immunoglobulin gene reshuffling. Both agreed and marked that one cellular event as earlier chatted is hindering DNA replication machinery by these guanine-rich assemblies as a piece of evidence. Recently published research articles covered the role of natural strategies such as homologous recombination and exclusion of edifice by helicases, which can pass G-quadruplex-mediated replication obstacle.[9] Such experimental and theoretical insight further provide fundamental intuitions on the routes monitoring practice when DNA looping is initiating pieces of machinery of transcription, recombination, and replication.

The mechanism of DNA loop formation is crucial and plays its role in many cellular mechanisms in different and adverse conditions. The above-stated routes are participating in governing cellular processes properly and can influence these routes of protein synthesis according to the needs.[10] The distance between the binding sites is a parameter and can affect the ability of DNA to form loops. The conformation of a particular sequence and other concerning features affect the deformability and bendability.[11] The cellular metabolic or environmental circumstances exaggerated by the extra- or intracellular signals and directly influence DNA loops. The site-specific protein-DNA binding is another phenomenon that deals with the protein-protein and protein-ligand interactions.[12] These biophysical interactions originate from different physiological states and influence many cellular processes, including

transcription, recombination, and replication.[13] Various biological molecules were applied during distinct binding topologies and in hyper-stable or hypo-stable loops for altering conformations. It is a well-known fact that the phenomenon of DNA looping alters looping behaviors, cell-to-cell variability, topologies, and earlier described interactions.[14] Here, author assumed that the mechanism of loop switching can be useful in controlling gene expression experimentally.

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Formulation of an Antidiabetic Herbal Capsule from Isolated Compounds of Ethanolic Extract of *Dregea Volubilis* and *Leptadenia Reticulata*

By Venkatesan Natarajan, Anton Smith. A,
Vishwanath. B.A & Suchitra. D

Abstract- The present investigation was aimed to formulate capsule formulations containing isolated compounds from *Dregea volubilis* and *Leptadenia reticulata*. In order to obtain anti diabetic formulations with more effective oral hypoglycemic activity, less side effects, increased patient compliance thereby providing multifaceted benefits. DVL (DV and LR isolated fraction was mixed in 1:1 ratio) capsules were formulated and the study was carried out for its anti-diabetic effect of STZ and HFD induced diabetic rats. Preformulation of capsules were observed as angle of repose and bulk density. Finished capsule formulations were evaluated for weight variation, pH, moisture content, disintegration time, *in vitro*-drug release percentage and *in vivo* anti diabetic studies. In our study showed empty capsule shell pH was observed as 3.62 and moisture content of capsule was found as <5 % w/w which indicated that there were less chances of microbial growth and capsule will not become soft. Filled capsule passed the test for uniformity of weight, all capsules disintegrated within 7 minutes.

Keywords: diabetes mellitus, polyphenolic compound, herbal formulation.

GJMR-B Classification: NLMC Code: WB 330



FORMULATION OF AN ANTI DIABETIC HERBAL CAPSULE FROM ISOLATED COMPOUNDS OF ETHANOLIC EXTRACT OF DREGEA VOLUBILIS AND LEPTADENIA RETICULATA

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Formulation of an Antidiabetic Herbal Capsule from Isolated Compounds of Ethanolic Extract of *Dregea Volubilis* and *Leptadenia Reticulata*

Venkatesan Natarajan ^α, Anton Smith. A ^σ, Vishwanath. B.A ^ρ & Suchitra. D ^ω

Abstract- The present investigation was aimed to formulate capsule formulations containing isolated compounds from *Dregea volubilis* and *Leptadenia reticulata*. In order to obtain anti diabetic formulations with more effective oral hypoglycemic activity, less side effects, increased patient compliance thereby providing multifaceted benefits. DVLR (DV and LR isolated fraction was mixed in 1:1 ratio) capsules were formulated and the study was carried out for its anti-diabetic effect of STZ and HFD induced diabetic rats. Preformulation of capsules were observed as angle of repose and bulk density. Finished capsule formulations were evaluated for weight variation, pH, moisture content, disintegration time, *in vitro*-drug release percentage and *in vivo* anti diabetic studies. In our study showed empty capsule shell pH was observed as 3.62 and moisture content of capsule was found as <5 % w/w which indicated that there were less chances of microbial growth and capsule will not become soft. Filled capsule passed the test for uniformity of weight, all capsules disintegrated within 7 minutes. Dissolution of capsule was found as 94.17%. DVLR possesses significant blood glucose lowering and cholesterol lowering activities. The improvements in the lipid profile in diabetic animals after treatment with DVLR could be beneficial in preventing diabetic complications, as well as improving lipid metabolism in diabetic patients. Formulation of DVLR is observed as more active against hyperglycemia and hyperlipidemia compared with standard drug metformin.

Keywords: diabetes mellitus, polyphenolic compound, herbal formulation.

I. INTRODUCTION

Medicinal plants are commonly known for their therapeutic value and free from side effects. Keeping this in view, the development of anti diabetic drug from the natural plants being a major thrust area has drawn the attention of the researchers in the field of natural product research because synthetic drugs may cause unwanted side effects. The rational design of novel drugs from traditional medicine offers

new prospects in modern healthcare. However, a scientific proof of the anti-diabetic activity of medicinal plants and phytopharmaceuticals with fewer side effects is still lacking. *Dregea volubilis* and *Leptadenia reticulata* belongs to the family of Asclepiadaceae which is widely used in Indian traditional medicines. In our previous study, isolated fractions of Dv-1 from ETDV [1] and Lr-1 from ETLR [2] showed promising hypoglycaemic activity and the compound has been confirmed by GC-MS and spectral analysis. The spectral analysis showed that the compounds are polyphenolic in nature. Isolated fractions Dv-1 from ETDV and Lr-1 from ETLR were combined and given a trivial name DVLR which would be used for further studies. In herbal medicine, plant based formulations are used to alleviate the diseases. But the most important challenges faced by these formulations arise because of their lack of complete evaluation. So evaluation is necessary to ensure the quality and the purity of the herbal product. It is very important to establish a system of evaluation for every plant medicine in the market, since the scope for variation in different batches of medicine is enormous. Nutrition is the provision, to cells and organisms, of the materials necessary (in the form of food) to support life. A poor diet can have an injurious impact on health, causing deficiency diseases. Herbal nutritional supplements provide essential nutrients that are not present or present in less amount in diet [3, 4]. Hence we formulate the DVLR capsules and the study was carried out for its anti-diabetic effect of STZ induced diabetic rats.

II. MATERIAL AND METHODS

a) Formulation and Evaluation of Capsules

Description and size of capsules are summarized in Table 1. 9el size of capsule purchased from capsule suppliers, Torpac, Fairfield, USA. Capsule especially made for administration of rats.

b) Preformulation studies

Preformulation studies were carried out for the investigation of physicochemical characteristics of a drug substance alone and in combination with excipients. The overall objective of preformulation testing was to generate information which will be useful in developing a stable dosage form.

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i. *Angle of Repose*

A funnel was kept vertically in a stand at a specified height above a paper placed on a horizontal surface. The funnel bottom is closed and 10 g of sample powder (DV and LR isolated fraction was mixed in 1:1 ratio) is filled in funnel. Then funnel was opened to release the powder on the paper to form a smooth conical heap, is found by measuring in different direction. The height of the heap was measured by using scale. The values of angle of repose are calculated by using the following formula:

$\tan \theta = h/r$ Where, h is height of the heap and r is radius of the heap.

ii. *Bulk Density*

A known quantity of powder was poured into the measuring cylinder carefully. The powder was levelled (DV and LR isolated fraction was mixed in 1:1 ratio) without compacting, if necessary and read the unsettled apparent volume, V_o , to the nearest graduated unit. Bulk density was calculated, in gm per ml, by the following formula.

Bulk density = Bulk Mass/ Bulk Volume.

c) *Filling of Capsule*

i. *Hand Operated Hard Gelatin Capsule Filling Machine*

The empty capsules are filled into the loading tray which is placed over the bed. By opening the handle, the bodies of the capsules are locked and caps separated in the loading tray itself, which is then removed by operating the lever. The weighed amount of the drug was mixed with sufficient quantity of excipients to be filled in the capsules and placed in powder tray already kept in position over the bed. The powders are spreaded with the help of a powder spreader so as to fill the bodies of the capsules uniformly to get 200 capsules. The excess of the powder is collected on the platform of the powder tray. Lowered the pin plate and moved it downward so as to press the powder in the bodies. The powder tray is removed and placed the caps on the holding tray in position. The caps are pressed with the help of plate with rubber top and operated the lever to unlock the cap and body of the capsules. The loading tray is removed and the filled capsules are collected in a tray.

d) *Quality Control Parameters for Capsule*

i. *Formulation of Capsule*

Each formulated capsule contains equivalent to 50 mg of DVLR and excipients 30 mg which was priorly grounded which are summarized in Table 2.

ii. *Determination of Moisture Content*

The test was performed by using KF instrument by Electro Lab. The sample prepared by mixing together the content of four capsules. For low water concentrations (< 0.1 %), the utilization of a titrant with a factor of less than 5 mg/mL recommended. An alternative to the direct volumetric titration are both the external extraction as well as the KF oven technique: during external extraction the sample is dissolved, During analysis by the KF oven technique the water released by heating the sample to an appropriate temperature and then transferred into a volumetric cell [5].

iii. *Determination of pH*

The pH value of a solution was determined potentiometrically by means of a glass electrode, a reference electrode and a digital pH meter. The pH meter was operated according the manufacturer's instructions. First the apparatus was calibrated using buffer of 4, 9 and 7 pH. One empty capsule was taken and dissolved in 100 ml demineralized water. The electrodes were immersed in the solution and the pH was measured [5].

iv. *Uniformity of Weight*

Twenty filled capsules were randomly selected and weighed to determine the average weight and were compared with individual capsule weight. The percentage weight variation was calculated [5].

e) *Dissolution Test for Capsule*

The dissolution test was performed for capsule using USP dissolution apparatus 2 by Electro Lab. The 900 ml of the pH - 7.2 phosphate buffer as dissolution medium was introduced into the vessel of the apparatus. For the capsules basket type dissolution apparatus was used. Temperature was maintained at $37.5^{\circ}\text{C} \pm 0.5^{\circ}\text{C}$ [5]. 10 ml of sample was withdrawn at 30, 45, and 60 time interval and replaced by same quantity of fresh buffer solution. The absorbance of samples was measured at 263 nm. The amount of percentage drug release was calculated by using the following formula [6].

$$\text{Concentration (mg)} = \frac{\text{Absorbance / Slope} \times \text{Dilution factor} \times \text{Total volume of dissolution bath}}{1000}$$

$$\% \text{ Drug Release} = \frac{\text{Concentration (mg)}}{\text{Labelclaim}} \times 100$$

f) *Disintegration Test for Capsule*

Disintegration test was performed with the help of the digital microprocessor based disintegration test apparatus by Electro Lab. One capsule was introduced into each tube and added a disc to each tube. The assembly was suspended in the water in a 1000 ml beaker. The volume of water was such that the wire mesh at its highest point is at least 25 mm below the surface of the water, and at its lower point was at least 25 mm above the bottom of the beaker. The apparatus was operated and maintained the temperature at $37.50 \pm 0.5^\circ\text{C}$. The time required to disintegrate all capsules and pass through wire mesh [6].

g) *Anti-diabetic Effect of DVLR on Plasma Glucose Concentration and Lipid Profile in STZ induced Diabetic Rats*

i. *Induction of Diabetes*

Male Wistar rats each weighing 180–220 g was obtained from Annamalai University at Chidambaram, Tamil Nadu, India. The guidelines of the CPCSEA of the Government of India were followed, and prior permission was granted from the Institutional Animal Ethics Committee (No. 842/CPCSEA). Rodent laboratory chow and water were accessed *ad libitum*, and rats were maintained on a 12 h light/dark cycle in a temperature regulated room ($20\text{--}25^\circ\text{C}$) during the experimental procedures. The fasted rats were injected intravenously with 50 mg/kg of STZ along with High Fat Diet (HFD). The HFD was freshly prepared everyday and the method of preparation is described by Devi, *et al.*, 2004 [7]. Control animals were provided with normal pellet chow (Lipton, India). After 3 days on high fat diet, animals were fasted overnight and diabetes is induced by STZ injection. The STZ was freshly dissolved in citrate buffer (0.01 M, pH 4.5) and kept on ice prior to use. One week after STZ administration, the rats with fasting blood glucose concentrations of over 200 mg/dl were considered to be diabetic and were used in the experiment.

ii. *Effect of DVLR on FBG and the Lipid Profile in Diabetic Rats*

Normal control and diabetic control rats were divided into four groups with six rats in each group. Group I and II are normal control and diabetic control rats received 1 ml of distilled water. Group-III diabetic rats received 50 mg/kg of DVLR. Group IV-diabetic rats received 50 mg/kg metformin. All the groups were treated orally for 21days. The filled capsules were administered by dosing syringe [8].

iii. *Assessment of Liver, Kidney and Pancreas Function*

Blood samples collected from all four groups were allowed to clot at room temperature. Serum was separated by centrifugation at 2500 rpm for 10 minute. The functional state of the liver, kidney and pancreas were assessed by estimating the biochemical

parameters of blood serum. After collecting the blood, the animals were sacrificed and their liver, kidney, pancreas was isolated, weighed and preserved in 10% formalin solution for histopathological studies.

h) *Histopathological Studies*

Histopathology the microscopic study of diseased tissue is an important tool in anatomical pathology, since accurate diagnosis of diabetes and other diseases usually requires histopathological examination of samples [9]. The isolated liver, kidney and pancreas were sliced into 5 mm pieces and fixed in neutral formalin solution (10%) for 3 days and washed in running water for about 12 hour. This was followed by dehydration with alcohol of increasing strength (70, 80 and 90%) for 12 hours each. Final dehydration was carried out using absolute alcohol with 3 changes at 12 minute interval. Cleaning was done by using xylin with changes at 15-20 minute interval. After cleaning, the pieces were subjected to paraffin infiltration in automatic tissue processing unit. The pieces were washed in running water to remove formalin completely.

i) *Statistical Analysis*

Data are expressed as $x \pm \text{SEM}$. Statistical analysis was performed by one-way analysis of variance (ANOVA). The least significant difference test was used for mean comparisons and $P < 0.05$ was considered to be statistically significant.

III. RESULTS

a) *Preformulation studies*

The latest developments in the fields of formulation science and technology offer new opportunities for filling liquid and semi-solid formulations in hard gelatin capsules. Hence we formulate the DVLR (trivial name) capsules and the study was carried out for its anti-diabetic effect of STZ induced diabetic rats. In our study an angle of repose of sample powder was found to be $30.88^\circ \pm 0.28$ ($n=3$) and Bulk density of powder sample was found to be 0.6675 ± 0.005 ($n=3$). Empty capsule shell pH was found to be 3.62 and the moisture content of capsule was found to be $< 5\%$ w/w. Filled capsule passed the test for uniformity of weight and DVLR capsules disintegration time was found to be 7 minutes. Percentage release of capsule was observed in Table 3 and Figure 1. From the data dissolution percentage of capsule was found to be 94.17 %.

b) *Effect of DVLR on FBG and the lipid profile in diabetic rats*

DVLR (50 mg/kg) produced a significant ($P < 0.05$) reduction in FBG as more as metformin in diabetic rats which is summarized in Table 4. Additionally DVLR also caused significant ($P < 0.05$) reduction in the level of triglyceride, cholesterol, LDL and significant ($P < 0.05$) improvement in HDL when compared to normal control

which was summarized in Table 4 and shown in Figure 2 and 3. The changes in mean percentage blood glucose in diabetic control group is 64.15% and DVLR, metformin treated groups are 47.62% and 48.41% respectively when compared to normal control. However the percentage rate of treated groups were decreased in compared to those of diabetic control. The changes in mean percentage of total cholesterol in diabetic control group is 32.08% and DVLR, metformin treated groups are 4.18% and 22.17% respectively. On the other hand, changes in mean percentage of triglyceride diabetic control group is 30.48% and DVLR, metformin treated groups are 5.15% and 25.35% respectively when compared to those of normal control. The changes in mean percentage of LDL in diabetic control group is 42.09% and DVLR, metformin treated groups are 2.80% and 19.78% respectively. On the other hand, changes in mean percentage of HDL in diabetic control group is 41.21% and DVLR, metformin treated groups are 1.12%, 14.5% respectively when compared to those of normal control.

c) *Histopathological Studies*

i. *Histopathology of Liver*

In histopathology studies of liver (Figure 4) normal control group showed structure of liver with sheets of hepatocytes separated by sinusoids cartial vein & portal tract appears. Diabetic control group showed the structure of liver with cords of hepatocytes and small area of lymphatous cells in diabetic control animals. DVLR treated group showed the structure of liver with sheets of hepatocytes separated by sinusoids cartial vein & portal tract appear in normal. Metformin treated group showed structure of liver with cords of hepatocytes. No morphological changes were observed.

ii. *Histopathology of Kidney*

In histopathology study of kidney (Figure 5), normal control group showed the structure of kidney with normal glomeruli and renal tubules. Diabetic control group showed the structure of kidney with inflammation of renal tubules and glomeruli. DVLR treated group showed the structure of kidney without inflammation of renal tubules and glomeruli. Metformin treated group showed the structure of kidney without inflammation of renal tubules and glomeruli.

iii. *Histopathology of Pancreas*

In histopathology study of pancreas (Figure 6) normal control group showed the structure of pancreas with the normal numbers and volume of the islets cells. Diabetic control group showed the structure of pancreas with the numbers of islets cells were severely decreased and severely swelled. DVLR treated group showed the structure of pancreas with the numbers of islets cells were moderately decreased and moderately swelled. Metformin treated group showed the structure of

pancreas with the numbers of islets cells were slightly decreased and slightly swelled.

IV. DISCUSSION

In recent years, interest in using hard gelatin capsules in developing and manufacturing medicines has increased considerably. This is most probably due to rapid advances in dosage forms for hard gelatin capsules. In tandem with this, the structural foundation of a new technology has been developed and realised in the form of efficient process machinery. The formulation of a rapid release hard gelatin capsule can be largely deduced from the physicochemical properties of the drug active. Usually, active compound simply mixed with the excipients and directly filled into the capsules. The costly process of granulation and compression can mostly be avoided. The choice available in terms of capsule type, the range of sizes and the capsule's colour or combination of colours, as well as the possibility of printing directly onto the capsule, means that patient compliance, product recognition and product differentiation can be markedly improved. A range of manual, semi-automatic and automatic filling machines are available for the manufacture of hard gelatin capsules. The latest developments in the fields of formulation science and technology offer new opportunities for filling liquid and semi-solid formulations in hard gelatin capsules. In our study empty capsule shell pH was observed as 3.62. Moisture content of capsule was found to be < 5 % w/w which indicates that there are less chances of microbial growth and capsule will not become soft. Filled capsule passed the test for uniformity of weight, all capsules disintegrated within 7 minutes. Percentage release of dissolution of capsule was found to be 94.17%. Administration of STZ caused rapid destruction of pancreatic cells in rats, which led to impaired glucose stimulated and inhibit insulin release, both of which are marked feature of type II diabetes [10]. The blood glucose-lowering effect of plant extracts is generally depends upon the degree of pancreatic β -cell destruction and useful in moderate streptozotocin induced diabetics [11]. Hypertriglyceridemia and hypercholesterolemia are the most common lipid abnormalities in diabetics [12]. In addition, hypertriglyceridemia is a metabolic consequence of hyperinsulinemia, insulin resistance and glucose intolerance [13]. STZ induced diabetic rats also showed the increases in plasma cholesterol and triglyceride concentrations [14], which may contribute to the development and progression of micro vascular and macro vascular complications, including neuropathy, nephropathy, cardiovascular and cerebrovascular diseases. The marked hyperlipidemia (increase in the level of lipid in the body) that characterizes the diabetic state which may be the consequence of the un-inhibited

actions of lipolytic hormones on fat depots [15]. DVLR possesses significant blood glucose lowering and cholesterol lowering activities. For this mechanism DVLR may be acutely stimulates it glucose uptake via activated protein kinase and extracellular signal-related kinase and produced great improvement of the altered lipid profile. It may also participate in the hypolipidemic activity by inactivating hepatic HMG-CoA reductase a key enzyme, in cholesterol synthesis. The improvements in the lipid profile in diabetic animals after treatment with DVLR could be beneficial in preventing diabetic complications, as well as improving lipid metabolism in diabetic patients.

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Table 1: Description and Size of Capsule

Description	Size 9el
Capsule Body Capacity	0.08 ml
Fill Weight (materials with density 1g/ml)	80 mg
External Diameter Maximum	2.65 mm
Length When Locked Maximum	23.2 mm
Weight Empty (Cap & Body) Average	17 mg
Colors Available	Clear & Opaque

Table 2: Quantity of Ingredients in DVLR Capsule

Ingredients	Strength (mg)
DV	25
LR	25
Carboxy methyl cellulose (CMC) Q.S	80

Table 3: Dissolution Study of DVLR Capsule

	DVLR		
	30 minutes %	45 minutes %	60 minutes %
1	65.72	80.17	93.75
2	66.12	82.27	94.17
3	65.10	81.50	92.97
4	64.98	80.97	94.07
5	65.27	82.15	93.10

Table 4: Effect of DVLR on Plasma Glucose Concentration, Cholesterol, Triglyceride, LDL and HDL for 21 days

Treatment	Fasting Blood Glucose (mg/dl)			Cholesterol (mg/dl)	Triglyceride (mg/dl)	LDL (mg/dl)	HDL (mg/dl)
	0 day	10 day	21 day				
Normal control	76.8 ± 4.9	87.9 ± 2.2	98.3 ± 3.9	91.6 ± 5.3	73.6 ± 3.6	83.10 ± 1.5	44.2 ± 0.9
Diabetic control	265.7 ± 3.8	257.6 ± 4.5	248.7 ± 4.4	134.5 ± 3.4	114.6 ± 6.8	143.5 ± 4.7	31.3 ± 3.1
DVLR (50 mg/kg)	263.6 ± 4.7	172.3 ± 5.2	92.2 ± 5.7*	95.6 ± 2.6*	77.6 ± 6.5*	85.5 ± 3.6*	49.7 ± 3.3*
Metformin (50mg/kg)	254.6 ± 4.2	188.8 ± 2.7	93.8 ± 4.8*	117.3 ± 3.4	98.6 ± 4.6	103.6 ± 6.3	38.6 ± 2.3

n=6. The statistical analysis was carried out using one way ANOVA followed by Dunnett's multiple comparison tests. *P < 0.05, compared to normal control group.

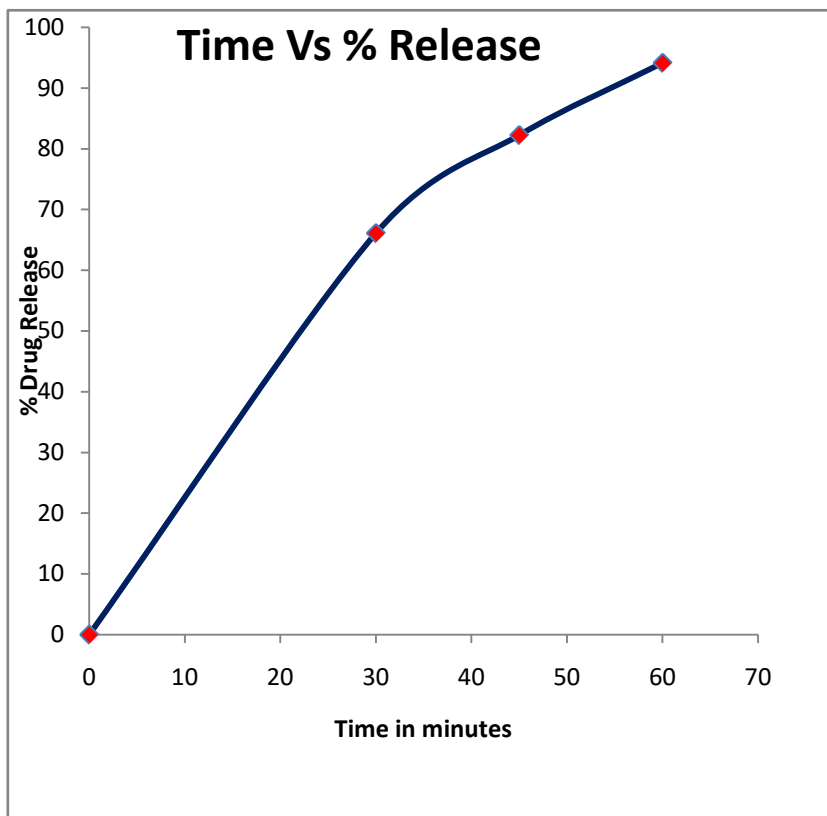


Figure 1: Dissolution profile of DVLR capsule

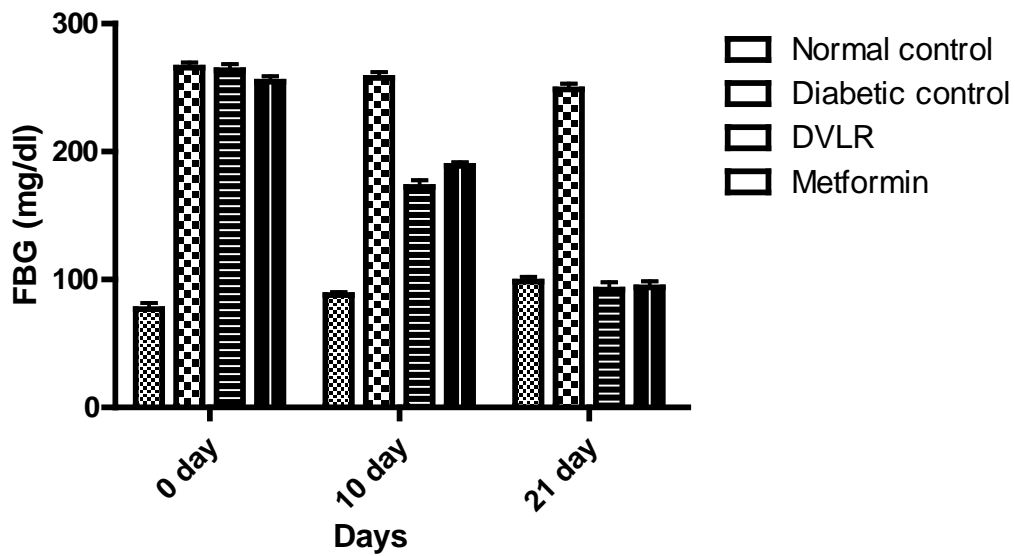


Figure 2: Effect of DVLR on Plasma Glucose Concentration

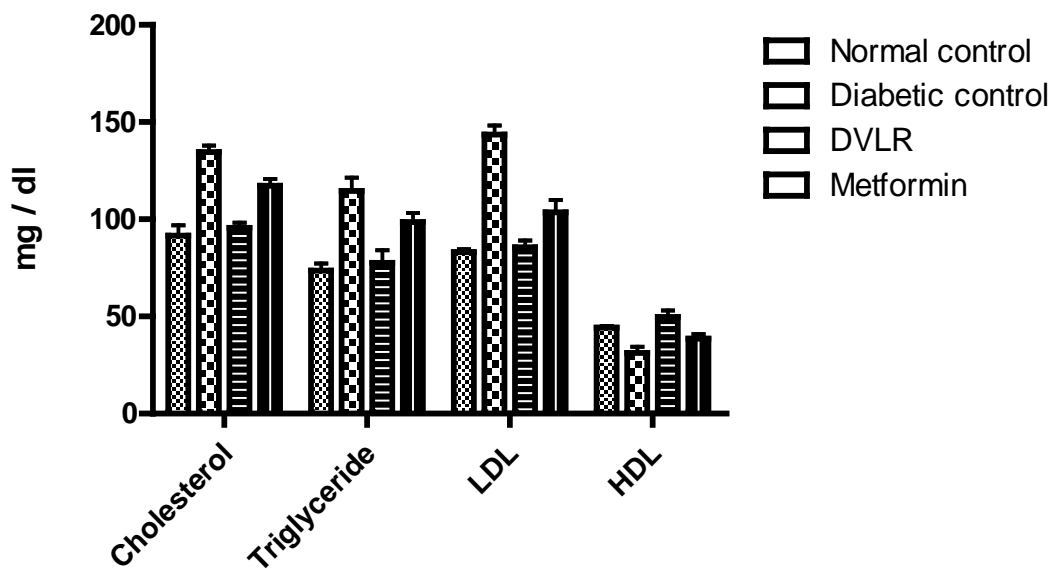
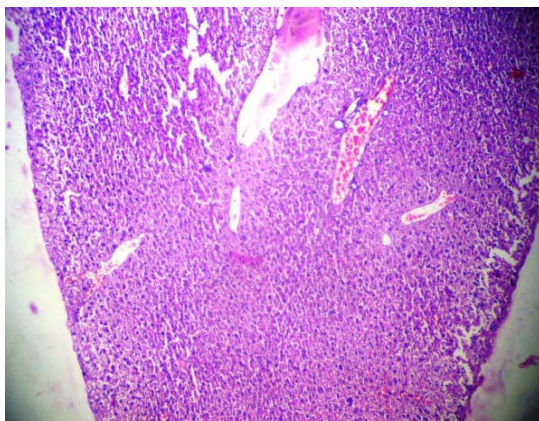
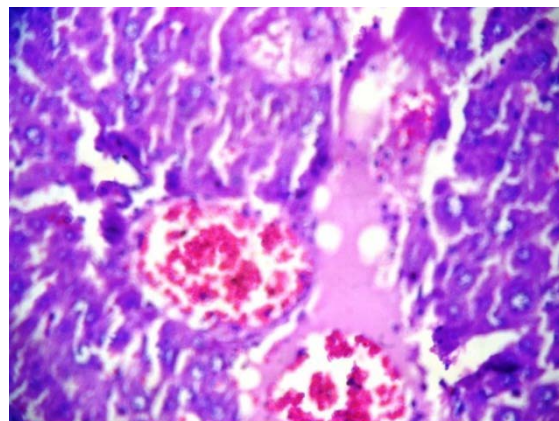


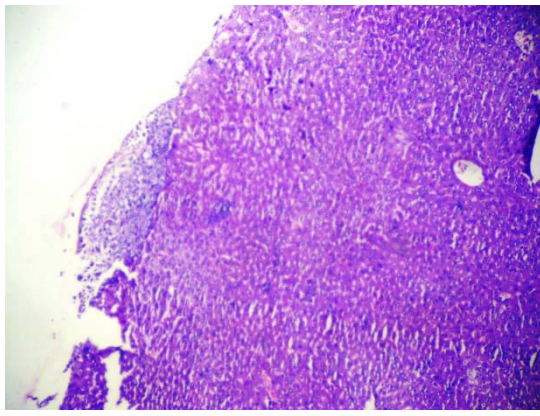
Figure 3: Effect of DVLR on Cholesterol, Triglyceride, LDL and HDL



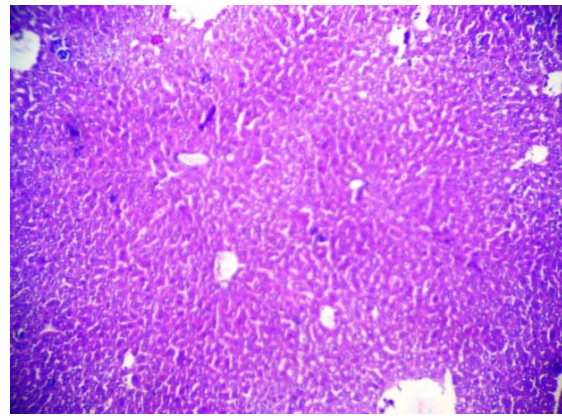
Normal control



Diabetic control

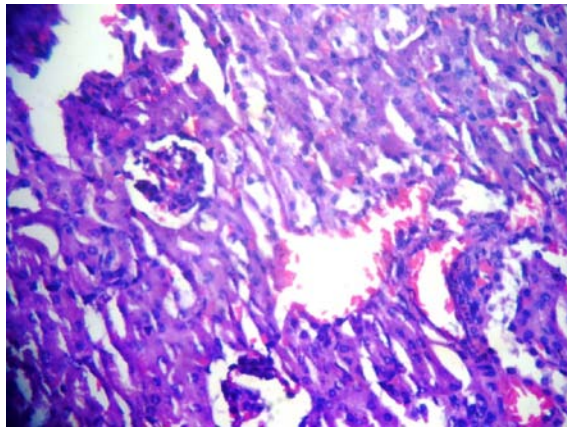


DVLR

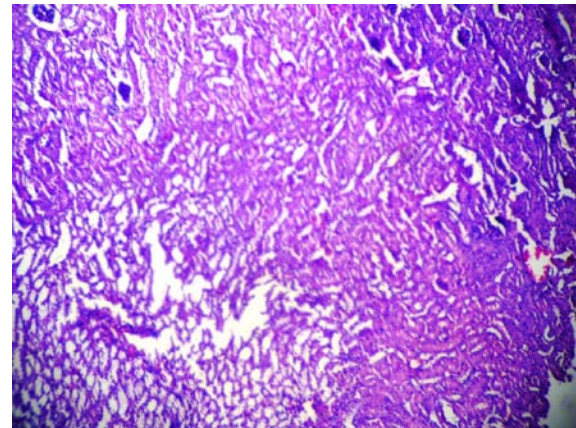


Metformin

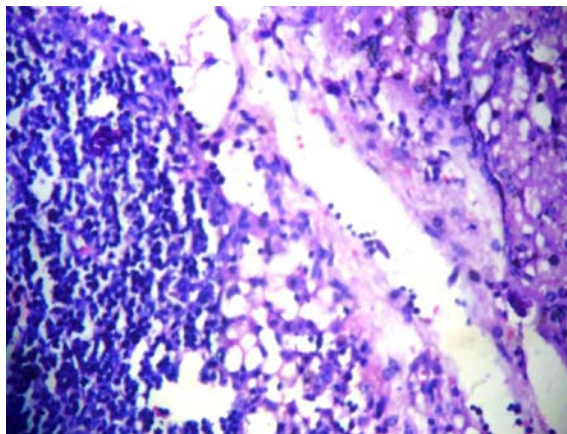
Figure 4: Histopathology of Liver



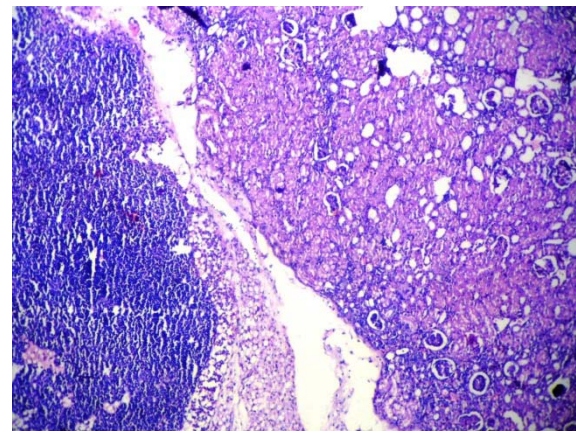
Normal control



Diabetic control



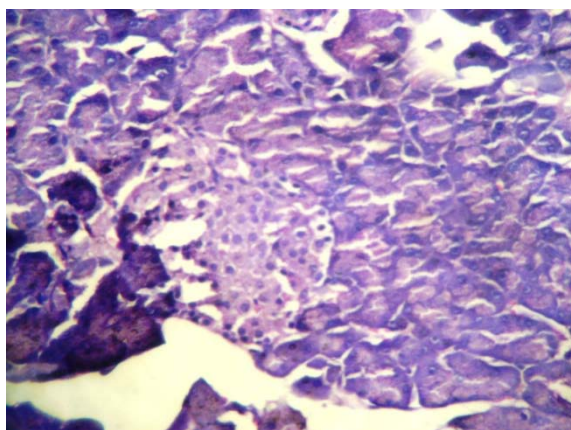
DVLR



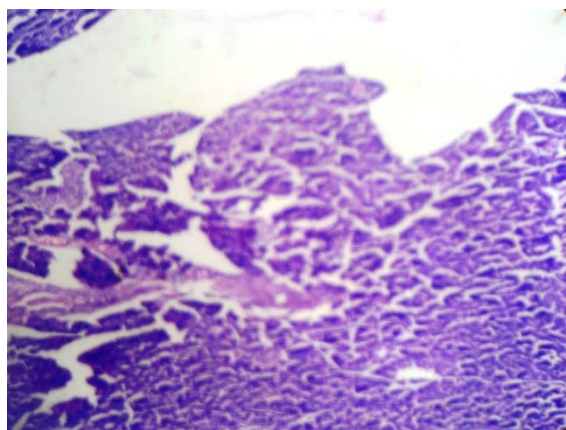
Metformin

Figure 5: Histopathology of Kidney

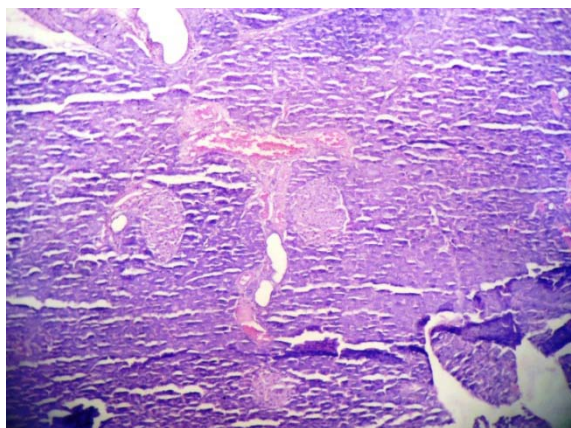




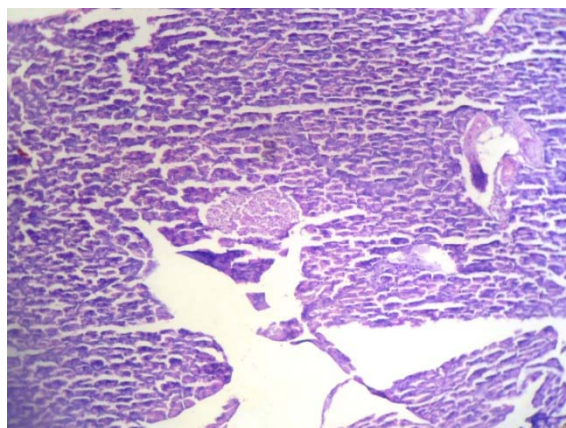
Normal control



Diabetic control



DVLR



Metformin

Figure 6: Histopathology of Pancreas



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Exclusive

Reputation



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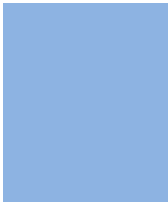
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Acknowledgments

Contributors to the research other than authors credited should be mentioned in Acknowledgments. The source of funding for the research can be included. Suppliers of resources may be mentioned along with their addresses.

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Authors can submit papers and articles in an acceptable file format: MS Word (doc, docx), LaTeX (.tex, .zip or .rar including all of your files), Adobe PDF (.pdf), rich text format (.rtf), simple text document (.txt), Open Document Text (.odt), and Apple Pages (.pages). Our professional layout editors will format the entire paper according to our official guidelines. This is one of the highlights of publishing with Global Journals—authors should not be concerned about the formatting of their paper. Global Journals accepts articles and manuscripts in every major language, be it Spanish, Chinese, Japanese, Portuguese, Russian, French, German, Dutch, Italian, Greek, or any other national language, but the title, subtitle, and abstract should be in English. This will facilitate indexing and the pre-peer review process.

The following is the official style and template developed for publication of a research paper. Authors are not required to follow this style during the submission of the paper. It is just for reference purposes.



Manuscript Style Instruction (Optional)

- Microsoft Word Document Setting Instructions.
- Font type of all text should be Swis721 Lt BT.
- Page size: 8.27" x 11", left margin: 0.65, right margin: 0.65, bottom margin: 0.75.
- Paper title should be in one column of font size 24.
- Author name in font size of 11 in one column.
- Abstract: font size 9 with the word "Abstract" in bold italics.
- Main text: font size 10 with two justified columns.
- Two columns with equal column width of 3.38 and spacing of 0.2.
- First character must be three lines drop-capped.
- The paragraph before spacing of 1 pt and after of 0 pt.
- Line spacing of 1 pt.
- Large images must be in one column.
- The names of first main headings (Heading 1) must be in Roman font, capital letters, and font size of 10.
- The names of second main headings (Heading 2) must not include numbers and must be in italics with a font size of 10.

Structure and Format of Manuscript

The recommended size of an original research paper is under 15,000 words and review papers under 7,000 words. Research articles should be less than 10,000 words. Research papers are usually longer than review papers. Review papers are reports of significant research (typically less than 7,000 words, including tables, figures, and references)

A research paper must include:

- a) A title which should be relevant to the theme of the paper.
- b) A summary, known as an abstract (less than 150 words), containing the major results and conclusions.
- c) Up to 10 keywords that precisely identify the paper's subject, purpose, and focus.
- d) An introduction, giving fundamental background objectives.
- e) Resources and techniques with sufficient complete experimental details (wherever possible by reference) to permit repetition, sources of information must be given, and numerical methods must be specified by reference.
- f) Results which should be presented concisely by well-designed tables and figures.
- g) Suitable statistical data should also be given.
- h) All data must have been gathered with attention to numerical detail in the planning stage.

Design has been recognized to be essential to experiments for a considerable time, and the editor has decided that any paper that appears not to have adequate numerical treatments of the data will be returned unrefereed.

- i) Discussion should cover implications and consequences and not just recapitulate the results; conclusions should also be summarized.
- j) There should be brief acknowledgments.
- k) There ought to be references in the conventional format. Global Journals recommends APA format.

Authors should carefully consider the preparation of papers to ensure that they communicate effectively. Papers are much more likely to be accepted if they are carefully designed and laid out, contain few or no errors, are summarizing, and follow instructions. They will also be published with much fewer delays than those that require much technical and editorial correction.

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It is necessary that authors take care in submitting a manuscript that is written in simple language and adheres to published guidelines.

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The title page must carry an informative title that reflects the content, a running title (less than 45 characters together with spaces), names of the authors and co-authors, and the place(s) where the work was carried out.

Author details

The full postal address of any related author(s) must be specified.

Abstract

The abstract is the foundation of the research paper. It should be clear and concise and must contain the objective of the paper and inferences drawn. It is advised to not include big mathematical equations or complicated jargon.

Many researchers searching for information online will use search engines such as Google, Yahoo or others. By optimizing your paper for search engines, you will amplify the chance of someone finding it. In turn, this will make it more likely to be viewed and cited in further works. Global Journals has compiled these guidelines to facilitate you to maximize the web-friendliness of the most public part of your paper.

Keywords

A major lynchpin of research work for the writing of research papers is the keyword search, which one will employ to find both library and internet resources. Up to eleven keywords or very brief phrases have to be given to help data retrieval, mining, and indexing.

One must be persistent and creative in using keywords. An effective keyword search requires a strategy: planning of a list of possible keywords and phrases to try.

Choice of the main keywords is the first tool of writing a research paper. Research paper writing is an art. Keyword search should be as strategic as possible.

One should start brainstorming lists of potential keywords before even beginning searching. Think about the most important concepts related to research work. Ask, "What words would a source have to include to be truly valuable in a research paper?" Then consider synonyms for the important words.

It may take the discovery of only one important paper to steer in the right keyword direction because, in most databases, the keywords under which a research paper is abstracted are listed with the paper.

Numerical Methods

Numerical methods used should be transparent and, where appropriate, supported by references.

Abbreviations

Authors must list all the abbreviations used in the paper at the end of the paper or in a separate table before using them.

Formulas and equations

Authors are advised to submit any mathematical equation using either MathJax, KaTeX, or LaTeX, or in a very high-quality image.

Tables, Figures, and Figure Legends

Tables: Tables should be cautiously designed, uncrowned, and include only essential data. Each must have an Arabic number, e.g., Table 4, a self-explanatory caption, and be on a separate sheet. Authors must submit tables in an editable format and not as images. References to these tables (if any) must be mentioned accurately.



Figures

Figures are supposed to be submitted as separate files. Always include a citation in the text for each figure using Arabic numbers, e.g., Fig. 4. Artwork must be submitted online in vector electronic form or by emailing it.

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Although low-quality images are sufficient for review purposes, print publication requires high-quality images to prevent the final product being blurred or fuzzy. Submit (possibly by e-mail) EPS (line art) or TIFF (halftone/ photographs) files only. MS PowerPoint and Word Graphics are unsuitable for printed pictures. Avoid using pixel-oriented software. Scans (TIFF only) should have a resolution of at least 350 dpi (halftone) or 700 to 1100 dpi (line drawings). Please give the data for figures in black and white or submit a Color Work Agreement form. EPS files must be saved with fonts embedded (and with a TIFF preview, if possible).

For scanned images, the scanning resolution at final image size ought to be as follows to ensure good reproduction: line art: >650 dpi; halftones (including gel photographs): >350 dpi; figures containing both halftone and line images: >650 dpi.

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TIPS FOR WRITING A GOOD QUALITY MEDICAL RESEARCH PAPER

1. Choosing the topic: In most cases, the topic is selected by the interests of the author, but it can also be suggested by the guides. You can have several topics, and then judge which you are most comfortable with. This may be done by asking several questions of yourself, like "Will I be able to carry out a search in this area? Will I find all necessary resources to accomplish the search? Will I be able to find all information in this field area?" If the answer to this type of question is "yes," then you ought to choose that topic. In most cases, you may have to conduct surveys and visit several places. Also, you might have to do a lot of work to find all the rises and falls of the various data on that subject. Sometimes, detailed information plays a vital role, instead of short information. Evaluators are human: The first thing to remember is that evaluators are also human beings. They are not only meant for rejecting a paper. They are here to evaluate your paper. So present your best aspect.

2. Think like evaluators: If you are in confusion or getting demotivated because your paper may not be accepted by the evaluators, then think, and try to evaluate your paper like an evaluator. Try to understand what an evaluator wants in your research paper, and you will automatically have your answer. Make blueprints of paper: The outline is the plan or framework that will help you to arrange your thoughts. It will make your paper logical. But remember that all points of your outline must be related to the topic you have chosen.

3. Ask your guides: If you are having any difficulty with your research, then do not hesitate to share your difficulty with your guide (if you have one). They will surely help you out and resolve your doubts. If you can't clarify what exactly you require for your work, then ask your supervisor to help you with an alternative. He or she might also provide you with a list of essential readings.

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6. Bookmarks are useful: When you read any book or magazine, you generally use bookmarks, right? It is a good habit which helps to not lose your continuity. You should always use bookmarks while searching on the internet also, which will make your search easier.

7. Revise what you wrote: When you write anything, always read it, summarize it, and then finalize it.

8. Make every effort: Make every effort to mention what you are going to write in your paper. That means always have a good start. Try to mention everything in the introduction—what is the need for a particular research paper. Polish your work with good writing skills and always give an evaluator what he wants. Make backups: When you are going to do any important thing like making a research paper, you should always have backup copies of it either on your computer or on paper. This protects you from losing any portion of your important data.

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11. Pick a good study spot: Always try to pick a spot for your research which is quiet. Not every spot is good for studying.

12. Know what you know: Always try to know what you know by making objectives, otherwise you will be confused and unable to achieve your target.

13. Use good grammar: Always use good grammar and words that will have a positive impact on the evaluator; use of good vocabulary does not mean using tough words which the evaluator has to find in a dictionary. Do not fragment sentences. Eliminate one-word sentences. Do not ever use a big word when a smaller one would suffice.

Verbs have to be in agreement with their subjects. In a research paper, do not start sentences with conjunctions or finish them with prepositions. When writing formally, it is advisable to never split an infinitive because someone will (wrongly) complain. Avoid clichés like a disease. Always shun irritating alliteration. Use language which is simple and straightforward. Put together a neat summary.

14. Arrangement of information: Each section of the main body should start with an opening sentence, and there should be a changeover at the end of the section. Give only valid and powerful arguments for your topic. You may also maintain your arguments with records.

15. Never start at the last minute: Always allow enough time for research work. Leaving everything to the last minute will degrade your paper and spoil your work.

16. Multitasking in research is not good: Doing several things at the same time is a bad habit in the case of research activity. Research is an area where everything has a particular time slot. Divide your research work into parts, and do a particular part in a particular time slot.

17. Never copy others' work: Never copy others' work and give it your name because if the evaluator has seen it anywhere, you will be in trouble. Take proper rest and food: No matter how many hours you spend on your research activity, if you are not taking care of your health, then all your efforts will have been in vain. For quality research, take proper rest and food.

18. Go to seminars: Attend seminars if the topic is relevant to your research area. Utilize all your resources.

19. Refresh your mind after intervals: Try to give your mind a rest by listening to soft music or sleeping in intervals. This will also improve your memory. Acquire colleagues: Always try to acquire colleagues. No matter how sharp you are, if you acquire colleagues, they can give you ideas which will be helpful to your research.



20. Think technically: Always think technically. If anything happens, search for its reasons, benefits, and demerits. Think and then print: When you go to print your paper, check that tables are not split, headings are not detached from their descriptions, and page sequence is maintained.

21. Adding unnecessary information: Do not add unnecessary information like "I have used MS Excel to draw graphs." Irrelevant and inappropriate material is superfluous. Foreign terminology and phrases are not apropos. One should never take a broad view. Analogy is like feathers on a snake. Use words properly, regardless of how others use them. Remove quotations. Puns are for kids, not grunt readers. Never oversimplify: When adding material to your research paper, never go for oversimplification; this will definitely irritate the evaluator. Be specific. Never use rhythmic redundancies. Contractions shouldn't be used in a research paper. Comparisons are as terrible as clichés. Give up ampersands, abbreviations, and so on. Remove commas that are not necessary. Parenthetical words should be between brackets or commas. Understatement is always the best way to put forward earth-shaking thoughts. Give a detailed literary review.

22. Report concluded results: Use concluded results. From raw data, filter the results, and then conclude your studies based on measurements and observations taken. An appropriate number of decimal places should be used. Parenthetical remarks are prohibited here. Proofread carefully at the final stage. At the end, give an outline to your arguments. Spot perspectives of further study of the subject. Justify your conclusion at the bottom sufficiently, which will probably include examples.

23. Upon conclusion: Once you have concluded your research, the next most important step is to present your findings. Presentation is extremely important as it is the definite medium through which your research is going to be in print for the rest of the crowd. Care should be taken to categorize your thoughts well and present them in a logical and neat manner. A good quality research paper format is essential because it serves to highlight your research paper and bring to light all necessary aspects of your research.

INFORMAL GUIDELINES OF RESEARCH PAPER WRITING

Key points to remember:

- Submit all work in its final form.
- Write your paper in the form which is presented in the guidelines using the template.
- Please note the criteria peer reviewers will use for grading the final paper.

Final points:

One purpose of organizing a research paper is to let people interpret your efforts selectively. The journal requires the following sections, submitted in the order listed, with each section starting on a new page:

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The discussion section:

This will provide understanding of the data and projections as to the implications of the results. The use of good quality references throughout the paper will give the effort trustworthiness by representing an alertness to prior workings.

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Specific editorial column necessities for compliance of a manuscript will always take over from directions in these general guidelines.

To make a paper clear: Adhere to recommended page limits.



Mistakes to avoid:

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- Submitting a manuscript with pages out of sequence.
- In every section of your document, use standard writing style, including articles ("a" and "the").
- Keep paying attention to the topic of the paper.
- Use paragraphs to split each significant point (excluding the abstract).
- Align the primary line of each section.
- Present your points in sound order.
- Use present tense to report well-accepted matters.
- Use past tense to describe specific results.
- Do not use familiar wording; don't address the reviewer directly. Don't use slang or superlatives.
- Avoid use of extra pictures—include only those figures essential to presenting results.

Title page:

Choose a revealing title. It should be short and include the name(s) and address(es) of all authors. It should not have acronyms or abbreviations or exceed two printed lines.

Abstract: This summary should be two hundred words or less. It should clearly and briefly explain the key findings reported in the manuscript and must have precise statistics. It should not have acronyms or abbreviations. It should be logical in itself. Do not cite references at this point.

An abstract is a brief, distinct paragraph summary of finished work or work in development. In a minute or less, a reviewer can be taught the foundation behind the study, common approaches to the problem, relevant results, and significant conclusions or new questions.

Write your summary when your paper is completed because how can you write the summary of anything which is not yet written? Wealth of terminology is very essential in abstract. Use comprehensive sentences, and do not sacrifice readability for brevity; you can maintain it succinctly by phrasing sentences so that they provide more than a lone rationale. The author can at this moment go straight to shortening the outcome. Sum up the study with the subsequent elements in any summary. Try to limit the initial two items to no more than one line each.

Reason for writing the article—theory, overall issue, purpose.

- Fundamental goal.
- To-the-point depiction of the research.
- Consequences, including definite statistics—if the consequences are quantitative in nature, account for this; results of any numerical analysis should be reported. Significant conclusions or questions that emerge from the research.

Approach:

- Single section and succinct.
- An outline of the job done is always written in past tense.
- Concentrate on shortening results—limit background information to a verdict or two.
- Exact spelling, clarity of sentences and phrases, and appropriate reporting of quantities (proper units, important statistics) are just as significant in an abstract as they are anywhere else.

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The following approach can create a valuable beginning:

- Explain the value (significance) of the study.
- Defend the model—why did you employ this particular system or method? What is its compensation? Remark upon its appropriateness from an abstract point of view as well as pointing out sensible reasons for using it.
- Present a justification. State your particular theory(-ies) or aim(s), and describe the logic that led you to choose them.
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Approach:

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Materials:

Materials may be reported in part of a section or else they may be recognized along with your measures.

Methods:

- Report the method and not the particulars of each process that engaged the same methodology.
- Describe the method entirely.
- To be succinct, present methods under headings dedicated to specific dealings or groups of measures.
- Simplify—detail how procedures were completed, not how they were performed on a particular day.
- If well-known procedures were used, account for the procedure by name, possibly with a reference, and that's all.

Approach:

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Use standard style in this and every other part of the paper—avoid familiar lists, and use full sentences.

What to keep away from:

- Resources and methods are not a set of information.
- Skip all descriptive information and surroundings—save it for the argument.
- Leave out information that is immaterial to a third party.



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The principle of a results segment is to present and demonstrate your conclusion. Create this part as entirely objective details of the outcome, and save all understanding for the discussion.

The page length of this segment is set by the sum and types of data to be reported. Use statistics and tables, if suitable, to present consequences most efficiently.

You must clearly differentiate material which would usually be incorporated in a study editorial from any unprocessed data or additional appendix matter that would not be available. In fact, such matters should not be submitted at all except if requested by the instructor.

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- Sum up your conclusions in text and demonstrate them, if suitable, with figures and tables.
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- Present a background, such as by describing the question that was addressed by creation of an exacting study.
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Approach:

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- Make a decision as to whether the tentative design sufficiently addressed the theory and whether or not it was correctly restricted. Try to present substitute explanations if they are sensible alternatives.
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- Recommendations for detailed papers will offer supplementary suggestions.

Approach:

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<i>References</i>	Complete and correct format, well organized	Beside the point, Incomplete	Wrong format and structuring



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