Annexure "E"

Information of Director of Training Centre

ANNEXURE – "E"

Information of Director of Training Centre

It shall be verified by the Head of the concerned Training Center,

Sr. No.	Particular	-	Information to be filled
01.	Name of the Director		Dr. Manisha Parag Ghurde
02.	Date of Birth		29/04/1974
03.	Address		Gulmohar Chs B – 108, Gavand Baug, Pokhran Road No.2 Thane (W)
04.	Tel. No./ Mob. No.		7722088789
05.	E-mail id		mipccoursecoordinator@gmail.com
06.	Nationality		Indian
07.	Qualification in details : (attach documentary proof)		B.H.M.S, M.D
08.	Teaching Experience / Health Sciences: Profession Experience (Attached document proof with signature of Head of the Institute. Also it is mandatory to attach self-attested Photocopy of the Experience Certificate of each Mentor in the Subject of concerned Fellowship/Certificate Course)		Teaching Experience : 24 Years Clinical Experience : 24 Years
09.	Present Appointment		Director / Course coordinator
10.	Publications (List & Proof)		Attached
11.	Post Graduate Teaching experience(Attach documentary evidence)		05 Years
12.	Any other relevant information		-

Date: - 23.05.22

Name & Sign. of Director
Dr. Manisha P. Ghurde

For the use of affiliated Training Center :

I have verified the eligibility of the above Director as per the criteria of eligibility prescribed by the University vide clause no.7 of the University Direction No. 05/2017 (Amended).

Sign & Stamp
Head of the Department
Date: 23.05.22

Training Centre Round Seal

Sign & Stamp
Dean/ Principal/ Director of Training Centre
Date: 23.05.22

Director
VRT's Madhavbaug Institute of
Preventive Cardiology &
Research Center

॥ श्री ॥

Reg No. E20159 (Mah)

Vd. Sane
Ayurvedic Education & Agricultural Research Trust (Regd.)
6, Rajput Kori Dnyati Mahal, Govandi, Mumbai - 400088. Tel : 022-2558 5306
www.madhavbaug.org

SANE

LETTER OF APPOINTMENT

To,
Dr. Manisha Ghurde
Thane.

Date: 13th April, 2017

Dear Dr. Manisha,

With reference to your application dated 1st April, 2017 and subsequent interview for the post of Course Coordinator, we are pleased to appoint you for the said post from **15th April, 2017.**

Your probation period is of 6 months and your appointment will be confirmed thereafter.

You will be deputed on VRT's Madhavbaug Institute of Preventive Cardiology with immediate effect.

Your monthly remuneration will be **Rs. 65,000/-** Professional tax, Provident Fund and other taxes applicable (if any) will be deducted as per Govt. Rule.

You will be abide by all the rules, regulations, terms and conditions, currently existing or modified / newly developed by Vd. Sane's Ayurvedic Education and Agricultural Research Trust.

You need to submit your joining report and a copy of Annexures regarding Remuneration, Job Responsibilities / KRAs, Terms and Conditions to us duly signed by you.

Congratulations on your appointment and a warm welcome to Vd. Sane's Ayurvedic Education and Agricultural Research Trust.

Thanking You.

Yours faithfully,

Dr. Vilas Potnis
Trustee
Vd. Sane's Ayurvedic Education and Agricultural Research Trust.

Madhavbaug Institute of Preventive Cardiology MIPC

Director
VRT's Madhavbaug Institute of
Preventive Cardiology &
Research Center

TRUE COPY

Joining Letter

To,

Date: 15.04.2017

The Trustee
Vd.sane's Ayurvedic Education & Agricultural research

This with reference of your Appointment letter Dated.14.04.2017 I hereby confirm that I have joined the duty today i.e.15th April 2017 before noon.

Submitted for your kind information and necessary action please.

Thanking you,

Yours Faithfully,

15/04/2017

(Dr.Manisha Ghurde)

Madhavbaug Institute of Preventive Cardiology
MIPC

TRUE COPY

Director
VRT's Madhavbaug Institute of
Preventive Cardiology &
Research Center

Vd. Sane's Ayurvedic Education and Agricultural Research Trust's
MADHAVBAUG INSTITUTE OF PREVENTIVE CARDIOLOGY
[A Chair of Maharashtra University of Health Sciences, Nashik]
MUHS
VRT

Date : 21/05/2022

Experience Letter

This is to certify that, Dr. Manisha P. Ghurde is working with us as a Director, since 20th July 2019 till date.

Dr. Vilas D. Potnis
Trustee
Vd. Sane's Ayurvedic Education
& Agricultural Research Trust

VAIDYA SANE AYURVEDIC EDUCATION & AGRICULTURAL RESEARCH TRUST
Reg No 20159 Mumbai

Director
VRT's Madhavbaug Institute of
Preventive Cardiology &
Research Center

MIPC

TRUE COPY

Office : Ishan Bldg. No. 2, 701, 7th floor, Gokhale Road, Naupada Thane (W) - 400602 I Tel. No.- 022-41235315/16 / 7722088789
Website- www.mipconline.com I Email - [redacted] / mipccoursecoordinator@gmail.com

॥ श्री ॥

Reg No. E20159 (MUM)

Vd. Sane
Ayurvedic Education & Agricultural Research Trust (Regd.)
6, Rajput Kori Dnyati Mahal, Govandi, Mumbai - 400088. Tel : 022-2556 5306
www.madhavbaug.org

SANE

PROMOTION LETTER

Date- 20th July 2019

Dr. Manisha Ghurde
Designation- Course Coordinator
Employee ID – 40296

Dear **Dr. Manisha,**

Congratulations!

Consequent to the review of your performance, we are pleased to inform that you are promoted as **Director- MIPC** with effect from **20th July'2019.**

All other terms and conditions of your appointment remain unchanged.

All the other terms and conditions as detailed in your appointment letter remain unchanged. We look forward to your valuable contributions and wish you all the very best for a rewarding career with the Trust.

Please sign the duplicate copy of this letter as a token of acceptance of the same.

For,

Vd. Sane's Ayurvedic Education and
Agricultural Research Trust

Dr. Rohit M. Sane
Secretary

VAIDYA SANE'S AYURVEDIC EDUCATION & AGRICULTURAL RESEARCH TRUST
Reg No E 20159 Mumbai

Madhavbaug Institute of Preventive Cardiology
MIPC

Received & accepted
Ghugde
22/07/2019

Director
VRT's Madhavbaug Institute of
Preventive Cardiology &
Research Center

TRUE COPY

Vd. Sane's Ayurvedic Education and Agricultural Research Trust's
MADHAVBAUG INSTITUTE OF PREVENTIVE CARDIOLOGY
[A Chair of Maharashtra University of Health Sciences, Nashik]

Date : 21/05/2022

Experience Letter

This is to certify that, Dr. Manisha P. Ghurde is working with us as a Course - coordinator, since 15th April 2017 till date.

Dr. Vilas D. Potnis
Trustee
Vd. Sane's Ayurvedic Education
& Agricultural Research Trust

Director
VRT's Madhavbaug Institute of
Preventive Cardiology &
Research Center

TRUE COPY

Office : Ishan Bldg. No. 2, 701, 7th floor, Gokhale Road, Naupada Thane (W) - 400602 | Tel. No.- 022-41235315/16 / 77220887
Website- www.mipconline.com | Email - [redacted] / mipccoursecoordinator@gmail.com

KONKAN EDUCATION & MEDICAL TRUST

Reg. No. E - 1129/TNA
Veer Savarkar-Marg, VIRAR (E) 401 305. Tal. Vasai, Dist. Thane, Maharashtra (INDIA)
Tel.: 0250 - 252 7773 / 252 9461 • E- mail - kcmtvhmc@hotmail.com

Ref. No. : KEMT/033/2017

Date :- 22/03/2017

TO WHOM SO EVER IT MAY CONCERN

This is to certify that Dr. (Mrs.) Manisha Parag Ghurde was working with KEMT's Virar Homoeopathic Medical College, Veer Savarkar marg Virar (E) 401305 as Principal from 01/11/2013 to 22/03/2017. She started her academic career with us as a Lecturer in department of Homoeopathic Repertory and case taking from 20/06/2001 and with her sincere efforts & excellent performance she was promoted to Reader from 21/06/2006 and then professor from 23/05/2015 in the same department and Principal of KEMT's Virar Homoeopathic Medical College, Virar (E). She was having 2 yrs. 4 mths. Previous Experience from Takhatmal Shrivallabh Homoeopathic Medical College & Hospital, Amravati. Her total experience is 18 yrs. 1 mth.

During her tenure with our College she performed all the tasks given to her with lot of determination, integrity and sincerity. She is an active and motivated person and sincerely performed her duties as a teacher as well as Principal. Besides in my opinion, she is a devoted, professional, hard working and innovative person.

Moreover, Dr. (Mrs.) Manisha Parag Ghurde has demonstrated excellent behaviour and attitude during her service and has maintained cordial relationship with everyone. We found her to be sincere, truthful, reliable and sociable. She was also a pleasant person to talk and work within a team.

She has willingly resigned from her services however, we still hope she will succeed in any path of career.

We wish her all the very best for her future endeavours.

TRUE COPY

Director
Madhavbaug Institute of Preventive Cardiology & Research Center

Madhavbaug Institute of Preventive Cardiology MIPC

Secretary,
Konkan Education & Medical Trust's
Virar (E), Dist. Palghar.

☎ : 677356

Takhatmal Shrivallabh Homoeopathic Medical College & Hospital

"Homoeo Sadan" Rajapeth, AMRAVATI - 444 606

Ref. No. ..... Date .....

EXPERIENCE CERTIFICATE

This is to certify that Dr. Ku. Manisha H. Dubey is working as a Demonstrator on Temporary basis in the Department of Obstetrics & Gynaecology of T.S.H.M. College and Hospital Since 26th Feb. 1998 to 30th June 2000.

I wish her each and every success in her endeavour in future.

PRINCIPAL,
Takhatmal Shrivallabh,
Homoeopathic Medical College,
Rajapeth, AMRAVATI.

Director
VRT's Madhavbaug Institute of
Preventive Cardiology &
Research Center

TRUE COPY

समचिकित्सा शल्य स्नातक

कु. मनिषा हनुमानप्रसादजी दुरे यांनी

अमरावती विद्यापीठाची समचिकित्सा शल्य स्नातक

परीक्षा हिवाळी १९९८ मध्ये श्रेणीत उत्तीर्ण केल्याबद्दल

त्यांना ही पदवी प्रदान करण्यात येत आहे.

कुलगुरू

अमरावती
28 FEB 1998

Amravati University

Bachelor of Homoeopathic Medicine & Surgery

This degree of Bachelor of Homoeopathic Medicine & Surgery

is conferred upon Ku. Manisha Hanumanprasadji Dube

on having passed the examination for the said degree

in Winter 1998

Director
Madhavbaug Institute of
ventive Cardiology &
Center

MIPC
Madhavbaug Institute of Preventive Cardiology

TRUE COPY

No 14111

CERTIFICATE OF REGISTRATION

MAHARASHTRA COUNCIL OF HOMOEOPATHY, MUMBAI

Similia Similibus Curentur

Certificate No. 26730

Date of Registration 06/06/1998

THIS IS TO CERTIFY THAT

Dr./ ~~Shri~~/ ~~Smt.~~/ Kumari DUBEY MANISHA HANUMANPRASADJI

has been duly registered under the Mumbai Homoeopathic Practitioners' Act, 1959 (Mumbai XII of 1960).

In witness whereof are herewith affixed the seal of the Maharashtra Council of Homoeopathy, Mumbai and the signature of the Registrar.

Subject to the provision of the Act, this certificate is valid until it is duly cancelled and the name of the practitioner is removed from the register.

05th June 2013

MIPC

Director
VRT's Madhavbaug Institute of
Preventive Cardiology &
Research Center

Signature of the Registrar

TRUE COPY

MAHARASHTRA COUNCIL OF HOMOEOPATHY

235, PIRAMAL MANSION, 3rd FLOOR, Dr. D.N. ROAD, FORT, MUMBAI - 1.
Phone No:- 270 3242, 270 3086, 270 4400 FAX NO:- (022) 2703086

E-mail:- alphamch@vsnl.net

Ref.No:- MCH/REG/ 26730/2001 Date:- 31-JAN-2001

FORM "K"

[See rule 12(5)]

ntimation to a registered /enlisted practitioner under section 26(1)(a)(iii) f the Bombay Homoeopathic and Biochemic Practitioner's Act, 1959.

To,

DR.DUBEY MANISHA HANUMANPRASADJI
'BAGESHREE' N/82
NEW CONGRESS NAGAR
D/ pin 444606
AMRAVATI
MAHARASHTRA

Dear Sir/Madam,

You are hereby informed that your certificate of Registration No. 26730 shall continue in operation subject to the provisions of section 26 unless it is duly cancelled under the Act.

Yours Faithfully,

Registrar,
Maharashtra Council of Homoeopathy,
Dr. D. N. Road, Mumbai-1.
Maharashtra State.

MHPC

Director
VRT's Madhavbaug Institute of Preventive Cardiology & Research Center

TRUE COPY

MAHARASHTRA UNIVERSITY OF HEALTH SCIENCES, NASHIK

We, the Chancellor, the Pro-Chancellor, the Vice-Chancellor, the Members of the Management Council and the Academic Council of the Maharashtra University of Health Sciences, Nashik, certify that

Shri/Smt. DUBEY MANISHA HANUMANPRASADJI

of Kakasaheb Mhaske Homoeopathic Medical College & Hospital, Ahmednagar

having been examined and found duly qualified for the

Doctor of Medicine in Homoeopathic Repertory

In Nov-2008 the said Degree has been conferred on him/her. In testimony whereof is set the seal of the said University.

Director
VPT's Madhavbaug Institute of Preventive Cardiology & Research Center
PRN 31082937/1

25th May 2009

महाराष्ट्र आरोग्य विज्ञान विद्यापीठ, नाशिक

आम्ही, महाराष्ट्र आरोग्य विज्ञान विद्यापीठाचे कुलपति, प्रकुलपति, कुलगुरु, व्यवस्थापन परिषद व विद्यापरिषद सदस्य प्रमाणित करतो की,
अहमदनगर येथील काकासाहेब म्हस्के होमिओपॅथिक वैद्यकीय महाविद्यालय आणि रुग्णालया चे/च्या

दुबे मनिषा हनुमानप्रसाद

हे/हया नोव्हेंबर - २००८ मध्ये

एम.डी. होमिओपॅथी (रेपर्टरी)

परीक्षा उत्तीर्ण झाल्याबद्दल त्यास ही पदवी प्रदान करण्यात येत आहे.
याची साक्ष म्हणून विद्यापीठाची अधिकृत मुद्रा यथे अंकित करण्यात येत आहे.

MAHARASHTRA UNIVERSITY OF HEALTH SCIENCES
(An ISO 9001:2008 Certified University)
Mhasrul, Nashik-422004
Tel. (0253) 2539191, Fax. (0253) 2539190
Website: www.muhs.ac.in E-mail: registrar@muhs.ac.in

MUHS

अ. का. सोनवणे
उप-कुलसचिव

No. MUHS/(UG)/E4/4103/2015

Date: 30/04/2015

To
The Principal,
Virar Homoeopathy Medical College,
Veer Savarkar Marg,
Virar (E), Tal – Vasai,
Dist – Thane – 401 303.

Sub :- Temporary approval to the appointment of teachers.

Ref :- Your letter No. KEM/001/2015 dated 20/04/2015

Sir,

With reference to the above cited subject regarding the proposal for approval to the appointment of teachers of your College under Local Selection Committee, I am directed to inform you that the Hon'ble Vice-Chancellor is pleased to grant approval to the appointment of following teachers as indicated below.

Sr. No.	Name of Teacher	Subject	Post	Status of approval
1	Dr. Manisha P. Sant	Physiology	Reader	w.e.f. date of joining i.e. 20/04/2015 temporary for one year only
2	Dr. Pooja Dalvi	Pathology	Lecturer	w.e.f. date of joining i.e. 20/04/2015 temporary for one year only
3	Dr. Jayanti A. Kulkarni	Surgery	Lecturer	w.e.f. date of joining i.e. 20/04/2015 temporary for one year only
4	Dr. Satishkumar R. Dubey	Obst. & Gync.	Lecturer	w.e.f. date of joining i.e. 20/04/2015 temporary for one year only
5	Dr. Parmar Bharat J.	Medicine	Professor	w.e.f. date of joining i.e. 20/04/2015 temporary for one year only
6	Dr. Burase S. J.	Medicine	Reader	w.e.f. date of joining i.e. 20/04/2015 temporary for one year only
7	Dr. Mahendrakumar Yadav	P.S.M.	Lecturer	w.e.f. date of joining i.e. 20/04/2015 temporary for one year only
8	Dr. Manisha P. Ghurde	Repertory	Professor	w.e.f. date of joining i.e. 20/04/2015 temporary for one year only
9	Dr. Barve Rajesh S.	Repertory	Reader	w.e.f. date of joining i.e. 20/04/2015 temporary for one year only

You are requested kindly to handover the copy of this letter to the above mentioned teachers.

Yours sincerely,

Director
VRT's Madhavbaug Institute of
Preventive Cardiology &
Research Center

MJPC

Registrar

Academic section (UG)

TRUE COPY

Details of Publication / Research Publication in Chronological Order:

Sr. No.	Title Of Paper / Book	Name Of Research Journal	Issue no. & Month Of Publication	Whether as a First Author Or Other
1	Impact of Comprehensive Diabetes Care (CDC) Management Program in Type II Diabetes Mellitus: A Retrospective Study	The Classical Science ISSN 2278-8646	Vol.13 Issue No.09 September 2019	Other
2	Efficacy of a polyheral oral formulation in the management of essential hypertension: an open label, pilot clinical study	The Classical Science ISSN 2278-8646	Vol.13 Issue No.10 October 2019	Other
3	Impact Of Comprehensive Diabetes Care (CDC) Management Program In Type Ii Diabetic Obese Patients: An Observational Study	The Classical Science ISSN 2278-8646	Vol.13 Issue No.10 October 2019	Other
4	Impact of Comprehensive Diabetes Care on Glycaemic Control with Reduction in Dependency of Oral Hypoglycaemic Medicines in Diabetic Patients: A Retrospective Study	The Classical Science ISSN 2278-8646	Vol.13 Issue No.10 October 2019	Other
5	Study Of The Liver And Renal Function In Patients Of Chronic Heart Failure Based On The Body Mass Index: A Retrospective Study	The Classical Science ISSN 2278-8646	Vol.13 Issue No.09 September 2019	Other
6	To Study Effect of Heart Failure Reversal Therapy (HFRT) on the Anthropometric Obesity Parameters in Patients of Chronic Heart Failure	The Classical Science ISSN 2278-8646	Vol.13 Issue No.09 September 2019	Other

Madhavbaug Institute of Preventive Cardiology MIPC

Director
VRT's Madhavbaug Institute of
Preventive Cardiology &
Research Center

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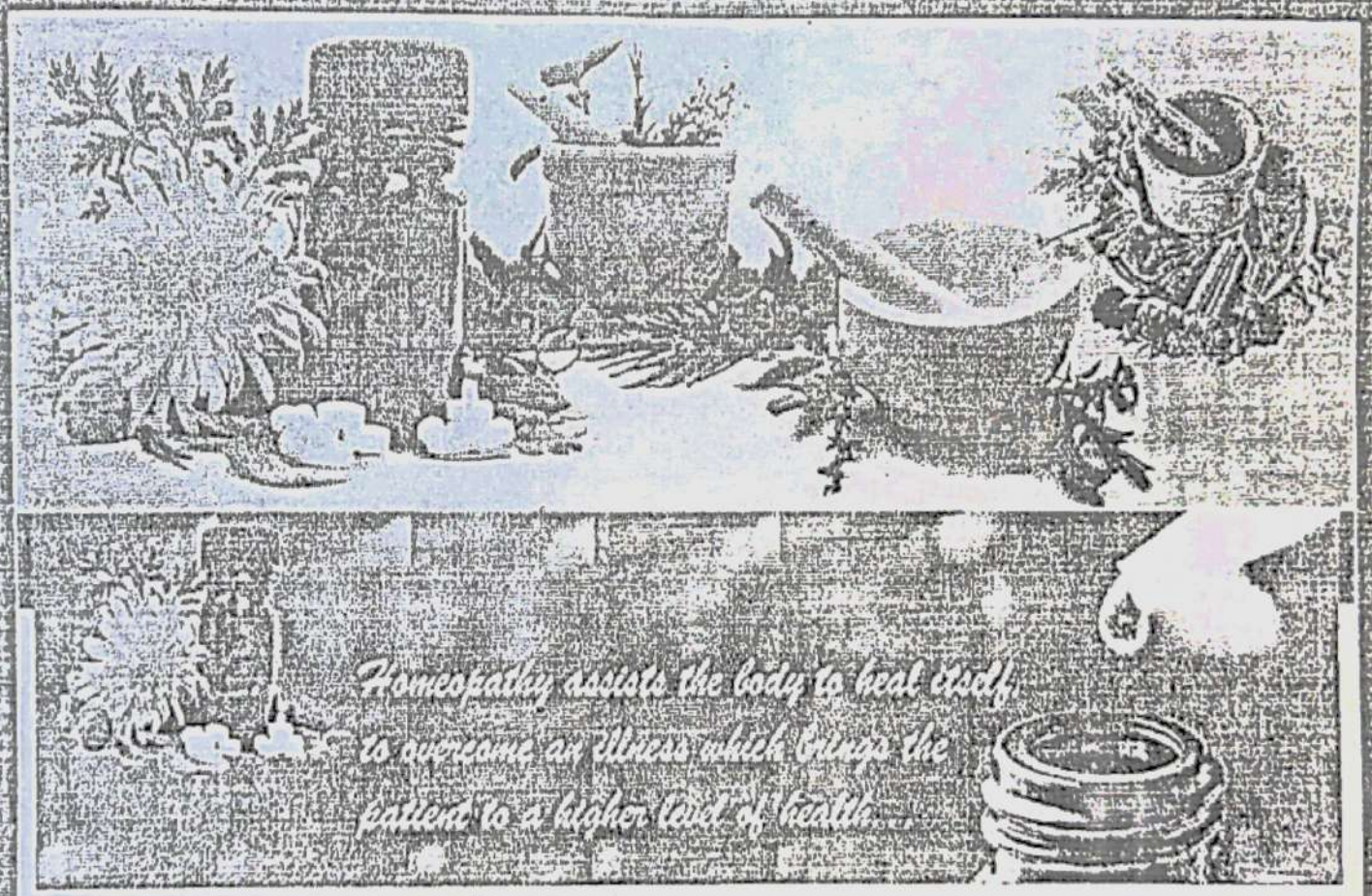
Postal Registration No
STR/038/2016-2018

ISSN 2278 - 8646
RNI. No. MAHMUL/2007/19492

THE CLASSICAL SCIENCE

A PEER REVIEWED MONTHLY MEDICAL JOURNAL

Vol.13 | Issue No 09 | SEPTEMBER 2019 | Rs. 25/-



Inside

धन्वंतरी नागरी सहकारी पतसंस्था मर्या., सातारा

Reg.No.SAT/SAT/RSR/(CR)/340/89-90 Dt.16-10-1989

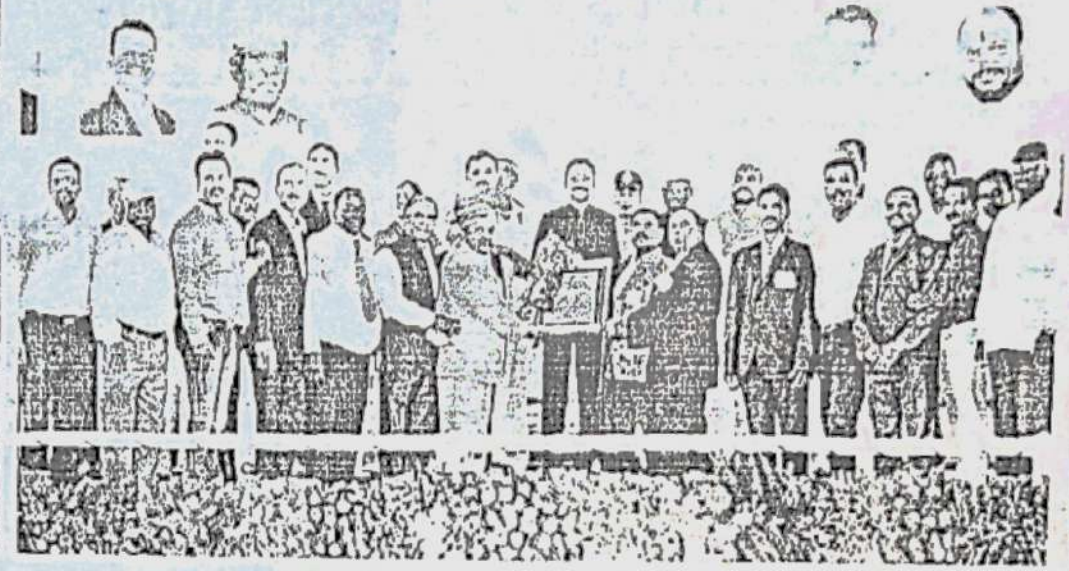
डॉ. रविंद्र भोसले
संस्थापक-चेअरमन

मुख्य कार्यालय : 'धन्वंतरी भवन', ९३ शनिवार पेठ,सातारा फोन :(०२१६२)२३८३४१

शाखा : सातारा, कोरेगांव, फलटण, कराड, निगडी-पुणे, धनकवडी पुणे

Website : www.dhanvantaripatsanstha.in Email : dhanvantari_patsanstha@rediffmail.com

डॉ. कांत फडतरे
व्हा. चेअरमन



संस्थेच्या सातारा शाखेत कामकाज सकाळी ९ ते रात्री ९

संस्थेच्या सातारा शाखेत कामकाज सकाळी ९ ते रात्री ९

सन २०१५-२०१६ करिता महाराष्ट्र शासनाचा पुणे विभागातून 'सहकार भूषण' पुरस्काराने मा. राज्यपालसो यांचे हस्ते गौरव

३०/०९/२०१९ अखेरील माहिती

१)	खेळत भाग भांडवल	२०७ कोटी ९९ लाख
२)	वसूल भाग भांडवल	१० कोटी ४३ लाख
३)	एकूण निधी	२४ कोटी ८२ लाख
४)	एकूण ठेवी	१७१ कोटी ७१ लाख
५)	एकूण येणे कर्ज	११४ कोटी ७८ लाख
६)	एकूण गुंतवणूक	९२ कोटी ८० लाख
७)	एकूण सभासद	९९४४
८)	सी.डी.रेशो	६१.२०%
९)	थकबाकी शेकडा प्रमाण	८.७१%
१०)	सी.आर.ए. आर.	४८.१९%

ठेवीचा प्रकार व मुदत	द. सा. द. शे
३० दिवस ते ९० दिवस	५ %
९१ दिवस ते १ वर्ष	६%
१ वर्ष ते ३ वर्ष मुदतीसाठी	७.५०%
पेन्शन ठेव (दरमहा व्याज	७.५०%
धनसंचय ठेव	३.००%
रिकरिंग ठेव	८.५०%
सेव्हिंग्ज ठेव	४%
दामदिप्पट ठेव	७.२५%
दामदुप्पट ठेव	७.२५%
जादा नागरिक मुदत ठेव	८.००%

६० वर्षे पूर्ण झालेल्या नागरिकांना १ वर्षापुढे मुदत ठेवीत व किमान २ वर्षापुढे पेन्शन योजनेत प्रचलित व्याजदरापेक्षा १/२% जास्त व्याज देण्यात येईल.

श्री. संजय यादवराव पवार
सरव्यवस्थापक

डॉ. कांत नारायण फडतरे
व्हा.चेअरमन

डॉ. रविंद्र नामदेव भोसले
संस्थापक- चेअरमन

Director
VPT's Madhavbaug Institute of Preventive Cardiology & Research Center

TRUE COPY

संचालक मंडळ

डॉ. श्री. लाहोटी, डॉ. शिरीष भोईटे, डॉ. अरविंद काळे, डॉ. शकील अत्तार, डॉ. सुनिल कोडगुले, डॉ. हेमंत शिंदे, डॉ. राजेंद्र जाधव, डॉ. राजेंद्र सारगर, डॉ. बाळासाहेब खडतरे, डॉ. सौ. सारिका सरकार, डॉ. अभिजीत भोसले.

आमचा संकल्प आपली सेवा - आपला मात्र सहकार्याचा हात हवा.

STUDY OF THE LIVER AND RENAL FUNCTION IN PATIENTS OF CHRONIC HEART FAILURE BASED ON THE BODY MASS INDEX: A RETROSPECTIVE STUDY

Dr. Rohit Sane[1], Dr. Gurudatta Amin[2], Dr.Manisha Ghurde[3], Dr. Snehal Dongre[1], Dr.Prabha Acharya[4] and Dr. Rahul Mandole*[1]

Department of Research and Development, Madhavbaug Hospital, Khopoli, India.
Department of Clinical Operations, Madhavbaug Hospital, Khopoli, India.
Medical Head, Madhavbaug Hospital, Khopoli, India
Department of Research and Development, Madhavbaug Hospital, Khopoli, India.
VRT's Madhavbaug Institute of Preventive Cardiology, Thane India.

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ABSTRACT

Background: Chronic heart failure (CHF) is known to affect hepatic and renal function adversely, but relevant Indian data is scarce. This study aimed to assess liver function tests (LFTs) and renal function tests (RFTs) of CHF patients and their relation to BMI status. **Methodology:** The retrospective study considered data of patients who consulted Madhavbaug clinics in Maharashtra, India between July-December 2018. Baseline LFTs and RFTs were analyzed wholly and based on BMI status, viz. normal-BMI, overweight and obese. **Results:** Of 147 patients, majority were males (74.15%) with mean age of 59.15±10.28 years. Based on BMI, three patient sub-groups were made: (56 with normal BMI, 60 were overweight and 30 were obese). Mean SGOT and SGPT were lower in obese group, but this was insignificant ($p>0.05$). OverallALP was increased in all CHF patients but was comparable in all three sub-groups ($p>0.05$). Mean direct bilirubin were above-normal in all sub-groups, but mean total and indirect bilirubin were normal. Mean A:G ratio was normal in all sub-groups. Total serum protein was below normal in all sub-groups, being lowest in overweight group, but these findings were insignificant ($p>0.05$). RFTs, viz. BUN and serum creatinine, were normal and comparable in all sub-groups ($p>0.05$). **Conclusion:** Mild elevation in direct bilirubin and notable ALP elevations were seen in CHF patients but their RFTs were normal. Mean LFTs and RFTs were comparable in patients with normal BMI, overweight or obese patients, indicating lack of association between BMI and hepatic or renalfunction

KEYWORDS: Liver function, Renal function, Body Mass Index, Heart Failure

INTRODUCTION

Cardiovascular diseases (CVDs) are few of the commonest reasons for morbidity as well as mortality in the world, and India is no exception. According to available data, CVD is the commonest cause of death in India. Chronic heart failure (CHF), which is reduced proficiency of the heart to pump the blood in the systemic circulation or inability to fill itself suitably with blood, affects about 10 million Indians. The prevalence of CHF is about 1% in thecountry.

CHF is associated with hepatic derangement due to liver congestion, which are generally asymptomatic but associated with deranged liver function tests (LFTs). Abnormal biochemical LFTs may be seen in CHF patients, but studies have shown variability in the findings. Also, if there are massive elevations seen in LFTs of CHF patients, these may be predictive ofadverse outcomes. There are studies based on the LFTs in CHF patients in the developed countries, but suchdatain the Indian setting is scarce.

Renal function is a known, but often neglected determinant of CHF prognosis. Studies have reported that renal insufficiency may be associated with poor CHF outcomes. However, there is a definite paucity of data with respect to the prevalence of renal insufficiency in CHF patients in the Indian context.

Body mass index (BMI), which is used to indicate the presence or absence of obesity in the population, is considered to be an important determinant of CHF risk and prognosis. Studies have shown that there is an increased risk of CHF development in patientswith increased BMI. Obesity, which is defined as BMI

more than 30 kg/m2, is considered an important risk factor for development of hypertension (HTN), diabetes mellitus (DM) and dyslipidemia, all of which are diseases which worsen the CHF prognosis. Literature search revealed that majority of CHF patients are obese, and this may be related to the impaired LFTs and RFTs in these patients. However, the specific impact of increasedBMI on the RFTs and the LFTs have not been studied in detail

In this retrospective study, we planned to assess the baseline LFTs and RFTs of CHF patients who visited the Madhavbaug clinics in India to tap the abnormalities in the hepatic or renal functioning. We also tried to assess these biochemical parameters based on the BMI status of the patients, after classifying the patients as those with normal BMI, overweight or obese

METHODOLOGY

This retrospective study was conducted utilizing the data of patients who suffered from CHF and visited the Madhavbaug clinics in the Indian state of Maharashtra. These CHF patients visited the clinics for check-up between July 2018 to December 2018. The case record files of these patients were assessed for completeness of the baseline characteristics, viz demographic details, anthropometric details, liver function tests (LFT) and the renal function tests (RFT). Data of only those patients was assessed who had completeness of the baseline records.

The CHF patients who came to the Madhavbaug clinics for the first time were subjected to general and systemic

examination, followed by blood collection to assess the LFTs and the RFTs. The blood was collected from the antecubital vein and sent to the laboratory for reporting. The biochemical values obtained were then entered in the case records of these patients after the test reports arrived. The LFTs which were taken into consideration from the baseline clinical records included alkaline phosphatase, serum glutamic-oxalacetic transaminase (SGOT), serum glutamic-pyruvic transaminase (SGPT), serum bilirubin (total, direct and indirect), albumin to globulin ratio and total protein levels. The baseline RFTs which were checked for in the medical records included serum creatinine and blood urea nitrogen (BUN). The normal range for the LFTs and RFTs were considered from standard textbooks and published literature (Table1)

The patients were classified based on the BMI as those having BMI in normal range, those who are overweight or obese based on the WHO classification followed worldwide. The BMI of between 18-24.9 kg/m2 were considered normal, between 25 to 29.9 kg/m2 were considered overweight while those above 30 kg/m2 were considered obese. The mean RFTs and LFTs values were calculated separately for these three BMI sub- groups and then the mean values werecompared.

Table 1: Normal Range for LFTs and RFTs.

Serum [illegible]	0.45
SGPT [illegible]	0-35
ALP [illegible]	30-120
Total bilirubin (mg/dl)	0.2-1
Direct bilirubin (mg/dl)	0.1
Indirect bilirubin (mg/dl)	1
Albumin Globulin ratio	1.5-2.5:1
Total protein (g/dl)	6-7.8 g
BUN (mg/dl)	7-20
Serum creatinine (mg/dl)	0.7-1.2

Data entry as well as coding was done in Microsoftexcel. Graphpadinstat software was utilized for data analysis. Categorical data was represented in the numeric form and continuous data was described as mean ± SD. The mean values of LFTs and RFTs were compared between the three subsets (normal BMI, overweight and obese) using Analysis of Variance (ANOVA) test. P value of less than 0.05 was considered statistically significant

RESULTS

147 patients visited the Madhavbaug clinics between the study period and had all the relevant details present in the case records. The data of these 147 patients was included in the study for analysis. The demographic details were recorded, and it was found that most of the patients were males (109 patients, 74.15%). The mean age of the CHF patients included in the study was 59.15 years, witha mean weight of 69.21 and mean heightof

1.6 meters, i.e. 160 centimeters. The mean BMI calculated forthe patients was 26.69 kg/m² (Table2)

Based on the BMI the patients were classified as per the WHO guidelines in three categories: those having normal BMI, those who were overweight and those who were obese (Table 3). 56 patients were found to

have normal BMI, 60 patients were over-weight while the remaining 30 were found to beobese.

Table 2: Demographic Details of CHF Patients (n=147).

Mean age (years)	59.15 ± 10.28
Median age (years)	59 (Range: 30-80)
Number of males	109 (74.15%)
Number of females	38 (25.85%)
Mean baseline weight (kg)	69.21 ± 14.39
Mean baseline height (meter)	1.6 ± 0.08
Mean Body mass index (BMI) (kg m2)	26.69 ± 4.97

Table 3: Classification of patients based on BMI (n=147).

Normal BMI (18.5-24.99 kg m-)	Overweight (25-29.99 kg m-)	Obese (>30 kg m-)
56	60	30

The mean values of all the LFTs and the RFTs were calculated based on the BMI-based subgroups and the comparison of these mean values was made between the three sub-groups. Amongst the LFTs, the mean SGOT and SGPT values were lower in the obese group, but this was not statistically significant (p>0.05). The overall ALP was increased in all the CHF patients. However, the mean ALP was comparable in all the three sub-groups (p>0.05) but was lowest in the normal BMI group. The mean direct bilirubin levels were found to be above the normal range in all the groups, but the total and the indirect bilirubin levels were in the normal range. Total bilirubin and indirect bilirubin were lowest in the obese group, and this was a statistically significant finding (p<0.05). The mean A:G ratio was found to be in the normal range, but the total serum protein was lower than the normal range in all the sub-groups. The mean A:G ratio was lowest but mean total protein was highest in the normal-BMI group, but these findings were statistically insignificant (p>0.05). The RFTs, viz. BUN and serum creatinine, were all in the normal range in all the groups, and comparable in the sub-groups (p>0.05) (Table 4).

Table 4: Comparison of Liver function test and Renal Function test according to BMI parameters in CHF patients.

Variables assessed	Overall mean values (n=147)	Normal BMI (18.5-24.99 kg/m²) (N=56)	Overweight (25-29.99 kg/m²) (N=60)	Obese (>30 kg/m²) (N=30)	P value
SGOT (U/L)	31.03 ± 15.04	34.01 ± 14.07	32.79 ± 17.96	27.67 ± 9.32	0.56
SGPT (U/L)	26.36 ± 15.05	27.46 ± 17.95	26.12 ± 13.60	24.87 ± 11.87	0.62
Alkaline phosphatase (ALP)	213.87 ± 82.1	210.16 ± 90.22	216.25 ± 70.28	215.84 ± 78.48	0.47
Total bilirubin	0.94 ± 0.41	1.04 ± 0.38	0.93 ± 0.39	0.79 ± 0.42	<0.001*
Direct Bilirubin	0.31 ± 0.19	0.35 ± 0.14	0.31 ± 0.11	0.33 ± 0.31	0.43
Indirect bilirubin	0.59 ± 0.3	0.66 ± 0.2	0.59 ± 0.31	0.48 ± 0.28	<0.001*
Albumin:Globulin ratio	1.57 ± 0.65	1.49 ± 0.37	1.65 ± 0.86	1.56 ± 0.57	0.27
Total protein	6.6 ± 0.94	6.6 ± 1.04	6.41 ± 1.22	6.47 ± 1.35	0.8
BUN	12.71 ± 8.11	13.5 ± 7.7	12.6 ± 6.36	13.51 ± 11.6	0.71
Serum creatinine	1.12 ± 0.44	1.12 ± 0.34	1.14 ± 0.45	1.1 ± 0.59	0.43

DISCUSSION

Obesity is an important risk factor for CVDs including CHF, and BMI is an important indicator for imminent or prevalent obesity. Multiple studies have found that CHF patients having BMI higher than the normal range are at an enhanced risk of mortality [1]. Higher than normal BMI is related to the development of multiple metabolic diseases including HTN and DM. Hence, directly and indirectly, BMI affects the CHF development and prognosis. CHF is also known to affect the liver and the renal function of the body according to many studies published in the developed countries, but it is not clearly known whether the same can be said about Indian CHF patients. It is also not clear that whether BMI plays a role in the deranged LFTs and RFTs in the CHF patients. Hence, the authors decided to analyze the available baseline data to evaluate whether CHF patients showed any biochemical derangement in LFTs or RFTs, bothas a whole as well as based on the BMI status of the patients.

The baseline LFT and RFT data of 147 CHF patients were analyzed. On evaluation of the whole data set, it was found that, out of the LFTs, the mean ALP and the mean direct bilirubin were raised above the normal range. The mean serum total protein was found to be mildly lowered in the CHF patients. However, the mean SGOT, mean SGPT, mean total bilirubin as well as indirect bilirubin, and the mean A/G ratio were in the normal range. An increase in the direct bilirubin is seen in parenchymal liver disease, which may be due to CHF. The mean ALP levels in this study were increased approximately twice the normal range. The increased central venous pressure (CVP) leads to passive congestion of the liver in CHF, which can lead to ALP elevation along with elevation of other liver enzymes.[2] Another important reason for elevated liver enzymes is decreased hepatic perfusion due to reduced cardiac output in CHF, thereby causing hepatocellular damage and elevated liver enzymes and bilirubin. However, the ALP is a non-specific enzyme which may be raised in bile duct obstruction, cirrhosis or even in bone disease. Hence, the raised ALP may not be linked with CHF, in the presence of normal SGOT and SGPT. The decreased mean protein, which was mild, can also be physiological due to aging or due to decreased liver function. Once again, the change in serum protein is mild and hence, inconclusive.

The RFTs which were noted down were serum creatinine and BUN, and both were in the normal range. This was in contrast to multiple studies in the western countries, which have shown that how long-term CHF can compromise renal functions. In a study by Tonelli et al., 33% of patients with CHF developed chronic kidney disease (CKD) in late life while the number was 32% in another study by Dammanet al. Just like forliver function, the main causes for compromisedrenal function in CHF patients are increased CVP and reduced renal blood flow. Initially, renal auto-regulation maintains the kidney function and this may be the reason why patients in our study had normal RFTs. However, glomerular filtration rate (GFR) declines over a period of time, and there is compromised renal function in the later stage oflife.[3]

The mean BMI for the CHF patients in this study was 26.69 kg/m^2, falling in the overweight category.[4] 60 of the 147 patients were overweight, 56 of them fell in the normal BMI category while 30 of them were in the obese category. It was found that all the values, except total bilirubin and indirect bilirubin, were comparable in the three BMI categories. Even though the total and the indirect bilirubin were significantly lower in the obese class of CHF patients, the values in all the groups were in the normal range and hence this statistical significance was clinically irrelevant. In our knowledge, this is one of the first studies which has tried to assess the LFTs and RFTs in CHF patients, based on the BMI and hence, this study holds a novelty factor.

The study had a few limitations. The study was carried

only in Western India, and hence patients of the whole country were not represented in the sample, creating region bias. Also, the sample size was low. A study with a bigger sample size, multiple centers and over a longer period may help in creating more robustevidence.

CONCLUSION

Mild elevation in direct bilirubin and notable elevations in ALP were seen in CHF patients but their RFTs were in the normal range. The mean LFTs and RFTs values were comparable in patients with normal BMI, overweight or obese patients indicating possible lack of association between BMI and hepatic or renal derangement in CHF patients. More evidence needs to be generated in Indian

CHF patients to create stronger evidence with regards to the LFTs and RFTs in CHF patients.

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To Study Effect of Heart Failure Reversal Therapy (HFRT) on the Anthropometric Obesity Parameters in Patients of Chronic Heart Failure

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Abstract

Background: Chronic heart failure (CHF) is a common cause of mortality and morbidity. Obesity influences the CHF development and prognosis. This study was conducted to assess effect of Heart failure reversal therapy (HFRT), a combination of panchakarma and allied therapies, on anthropometric parameters in CHF patients. ***Methodology:*** This retrospective study was conducted on data of patients who visited Madhavbaug clinics in Maharashtra, India between July-December 2018. Selection was based upon the availability of complete baseline (day 1 of HFRT) and follow-up data (day 30 of HFRT) of CHF patients who were admitted for minimum 5 days for HFRT. ***Results:*** Out of 147 patients, 74.15% were males with mean age 59.15±10.28 years. There was statistically significant decrease ($p<0.05$) in both mean BMI and abdominal girth at day 30 of HFRT. 42 of 147 patients (28.57%) had hypertension (HTN) with CHF, 22 patients (14.97%) had diabetes mellitus (DM) and 61 patients (41.49%) had both HTN and DM. In all these sub-groups, mean BMI and abdominal girth was significantly decreased ($p<0.05$) at day 30. Strong positive correlation was found between BMI and abdominal girth on day 1 ($R=0.9$, $P<0.05$) and day 30 ($R=0.83$, $P<0.05$) by Pearson's correlation. Similar correlation was found between the two parameters in subsets of CHF patients having HTN or DM or both DM and HTN ($p<0.05$). ***Conclusion:*** HFRT decreased BMI and abdominal circumference significantly in CHF patients, irrespective of the presence of HTN or DM. Both the anthropometric parameters correlated strongly in all co-morbidity subsets of CHF patients.

Keywords: HFRT, Obesity, Body mass Index, Abdominal Girth, Comorbidity

Introduction

Globally, cardiovascular diseases (CVDs) are few of the commonest causes of morbidity and mortality and the picture in India matches the global scenario. In the true sense, CVD has become the commonest cause of death in the country.[1] Chronic heart failure (CHF) is an intricate clinical syndrome which involves reduction in the ability of the heart to pump the blood in the systemic circulation or inability to fill itself appropriately with blood.[2] Approximately 8-10 million Indians are suffering from CHF, with an estimated prevalence of 1%.[3] There are well-known guidelines which talk about different pharmacological agents like angiotensin-converting enzyme (ACE) inhibitors, angiotensin receptor blockers (ARBs), vasodilators as well as beta blockers for the management of CHF. However, despite these multiple treatment options, the CHF mortality in India is as high as 20%- 30%.[4] Hence, there is a need of new treatment modalities which will improve the prognosis of CHF.

The role of obesity in the development or the CHF is widely debated. According to the Framingham Study there is an enhanced risk of developing CHF in people having elevated body mass index (BMI) (5% risk in men and 7% risk in women for every rising point of BMI).[5] Though there are doubts over the role of obesity as a solitary risk factor in the CHF development as well as prognosis, it is a proved fact that obesity is associated indirectly or directly in the

development of hypertension, type II diabetes mellitus and dyslipidemia, all of which are risk factors for CHF progress and development.[5] Hence, there needs to be development of therapeutic options which can help control obesity, benefitting the patients of CHF.

Physicians practicing alternative medicine believe that in the chronic stage of heart failure, use of *panchakarma* therapy (a 5- step procedure for delivering internal body purification) is an effective add-on therapy.[7] Heart failure reversal therapy (HFRT), also known as *sampurnahrudayshudhikaran*(SHS) therapy, is a blend of herbal treatment with panchakarma and allied therapeuticmodalities.[8-10] The techniques utilized in HFRT include snehana (massage), swedana (passive heat therapy) and basti (medicated enema), which are known to free the body from the toxins.

There has been some recent published evidence on the effect of the HFRT therapy on CHF patients. However, there is a paucity of data on the specific effect of HFRT on the modifiable anthropometric parameters for obesity in the CHF patients, which are BMI and abdominal circumference. Though BMI is a commonly utilized parameter to monitor obesity in the population, it does not give information on the adipose tissue distribution in an individual. Abdominal obesity, which is indicated by waist circumference, plays a crucial role in the cardiovascular risk assessment. Major health organizations like World Health Organization (WHO) have also suggested the combination of BMI as well as abdominal obesity to determine the distribution of adipose tissue in a more profoundway.[11]

In this retrospective study, the effect of HFRT was analyzed on BMI as well as waist circumference in CHF patients, to know the impact of HFRT on both the generalized body fat as well as on the abdominal obesity. We also assessed the correlation of the two anthropometric obesity parameters to check whether they go hand- in-hand, both before as well as after HFRT intervention

Methodology

This was a retrospective study conducted on the data of the patients who visited the Madhavbaug clinics in Maharashtra, India between July 2018 to December 2018. The data of only those patients was considered who had been administered HFRT over minimum 5 days of admission in the Madhavbaug clinics. Cases were identified, and data was assessed from the medical records of Madhavbaug clinics in Maharashtra. The selection was based upon the availability of complete relevant baseline data (day 1 of HFRT) and follow-up data (day 30 of HFRT) of the patients. The information about co-morbidities, if any, were noted down from the medicalrecords.

The HFRT is an amalgamation of panchakarma as well as allied therapies. HFRT uses different oils and decoctions, which constitutes of a 4-step procedure, described below in table 1.

Table 1: Study Treatment: Heart Failure Reversal Therapy (HFRT)

Step of HFRT	Type of Therapy	Herbs used for therapy	Duration of Therapy
Snehana	Massage of external [illegible] upper strokes directed towards heart	[illegible] (Oil [illegible])	[illegible] minutes
Swedana	Passive heat therapy	[illegible] group of ten herbal [illegible] with [illegible]	10-15 minutes [illegible] 3-4 minutes [illegible] procedure
Hrudayadhara	[illegible] therapy [illegible]	[illegible]	[illegible]
Basti	Medicated enema [illegible] should be [illegible] for [illegible] minutes for maximum absorption	[illegible] (Oil [illegible] extract)	[illegible] minutes

On the first day of hospital admission before starting HFRT, the BMI was evaluated by taking into consideration the height and the weight of the patients and using the formula: weight in kilograms/(height in meters)^2. The abdominal girth of patients was measured on day 1 before initiating HFRT using a measuring tape and noted down in medical records. In a similar way, the measurements of height, weight and abdominal girth were done on day 30 from HFRT initiation and the comparison with the baseline BMI and abdominal girth was done.

Data was entered and coded in Microsoft Excel spreadsheet. GraphpadInstat software was used to analyze the data. Categorical data were represented in the numeric form and continuous data were presented as the mean ± SD. Paired t-test was used to assess the difference between the values at baseline and 30th day after treatment initiation. Correlation between BMI and abdominal girth was calculated using Pearson's correlation coefficient. P value < 0.05 was considered statistically significant.

Results

A total of 147 patients' data was included in the study for analysis. The demographic details were compiled, and it was found that majority of the patients were males (74.15%). The mean age of the CHF patients was 59.15 years, with a mean baseline weight of 69.21 kilograms and mean height of 1.6 meters (Table 2).

Table 2: Demographic Details of CHF Patients (n=147)

Mean age (years)	59.15 ± 10.28
Median age (years)	59 (Range: 30-80)
Number of males	109 (74.15%)
Number of females	38 (25.85%)
Mean baseline weight (kg)	69.21 ± 14.39
Mean baseline height (meter)	1.6 ± 0.08

On comparing the mean BMI of all CHF patients between day 1 and day 30 of HFRT treatment, there was statistically significant decrease, assessed by paired T test. Similar findings were noted for mean abdominal girth, with statistically significant decrease at day 30. 42 of the 147 patients (28.57%) had hypertension (HTN) associated with CHF, 22 patients (14.97%) had type II diabetes mellitus (DM) and 61 patients (41.49%) had both HTN and DM along with CHF. In all these sub-groups, the mean BMI and mean abdominal girth was found to be significantly decreased at day 30 compared to that on day 1. (Table 3) **Table 3: Change in Anthropometric Obesity Parameters in Patients of CHF based on co-morbidities**

		At 1st observation	On 30th treatment	P value
All CHF patients [N=147]	Mean BMI (kg/m2)	26.60 ± 4.05	25.16 ± 5.05	0.01*
	Mean Abdominal girth (cm)	98.82 ± 12.74	93.68 ± 12.36	0.01*
CHF with Hypertension (HTN) [N=42]	Mean BMI (kg/m2)	26.67 ± 4.64	25.10 ± 5.05	0.01*
	Mean Abdominal girth (cm)	[illegible]	[illegible]	0.01*
CHF with Diabetes mellitus (DM) [N=22]	Mean BMI (kg/m2)	25.76 ± 6.45	24.46 ± 6.25	0.01*
	Mean Abdominal girth (cm)	96.45 ± 15.47	91.44 ± 14.96	0.01*
CHF with both HTN and DM [N=61]	Mean BMI (kg/m2)	27.31 ± 4.83	25.66 ± 5.44	0.01*
	Mean Abdominal girth (cm)	101 ± 12.9	95.79 ± 12.35	0.01*

P<0.05 considered significant by Paired T test

s Pearson Correlation Coefficient: R=0.9 (Strongcorrelation

Pearson Correlation Coefficient: R=0.83 (Strongcorrelation)

On subgroup correlation analysis based upon the associated co-morbidities, we found strong correlation between BMI and abdominal girth in subsets of CHF patients having only HTN, only DM or both DM and HTN, and all these correlations were statistically significant.Table 4: Correlation between BMI and Abdominal girth in patients of CHF with various co-morbiditie

Obesity poses as a risk factor for multiple CVDs, prominent of which are CAD and CHF. BMI is considered as an important indicator of sedentary lifestyle as well as impending or prevalent obesity. Many studies have shown that CHF patients having high BMI are at an increased risk of mortality.[12,13] Abdominal obesity, indicated by calculating the abdominal girth, is associated with development of multiple metabolic diseases like HTN and DM. These metabolic diseases are known risk factors for not only the development of CHF but also alters the prognosis. Hence, measuring of the anthropometric obesity indicators, which are BMI and abdominal girth, are equally important to predict the development or prognosis of CHF.

The existing treatment modalities have positive effects on the cardiovascular parameters but when it comes to their effect on BMI or abdominal girth, none of the drugs of CHF are known to be affecting them. There is certainly a dire need of modalities which can help modify these anthropometric parameters, which may directly and indirectly help in making the CHF prognosis more positive. Physicians practicing alternative medicine utilize panchakarma therapy as an add-on therapy for treatment of CHF and HFRT is a combination of panchakarma with allied therapies.[14] However, the effect of HFRT on the specific anthropometric parameters in patients of CHF are not well established, and no study has taken the co-morbidities besides CHF into consideration. Hence, it was thought to evaluate the effect of HFRT on BMI and abdominal girth in CHF patients, and also analyze

Day of assessment	Comorbidity seen	R (Correlation coefficient)	Interpretation	P value
Day 1 of HFRT	All CHF patients [N=147]	0.9	Strong positive correlation	<0.01*
	CHF with Hypertension (HTN) [N=42]	0.85	Strong positive correlation	<0.01*
	CHF with Diabetes mellitus (DM) [N=22]	0.91	Strong positive correlation	0.01*
	CHF with both HTN and DM [N=61]	0.91	Strong positive correlation	0.01*
Day 30 of HFRT	All CHF patients [N=147]	0.83	Strong positive correlation	<0.01*
	CHF with Hypertension (HTN) [N=42]	0.8	Strong positive correlation	<0.01*
	CHF with Diabetes mellitus (DM) [N=22]	0.93	Strong positive correlation	<0.01*
	CHF with both HTN and DM [N=61]	0.8	Strong positive correlation	<0.01*

Discussion

the data based on the subgroups suffering from HTN or DM orboth.

In this study, we assessed the effect of HFRT, a novel treatment modality, in CHF patients, on the obesity parameters of BMI and abdominal girth, after 30 days of HFRT initiation. It was found that HFRT significantly lowers the BMI and abdominal girth at day 30, compared to the baseline. The sub-group analysis to assess the effect of HFRT in CHF patients suffering from DM and HTN, separately and together, yielded positive results. This was done to evaluate whether any underlying metabolic disease will affect the positive effect of HFRT on the anthropometric measurements, which was not the case. Hence, irrespective of the underlying metabolic disease of HTN and DM, HFRT may benefit the patients based on BMI and abdominal girth.

HFRT comprises of *Snehana*(external oleation or massage), *Swedana*(passive heat therapy), *Hridaydhara*(decoction dripping therapy) as well as *Basti* (per rectal drug administration). Published literature states that the sympathetic nervous system is activated in obesity.[14] It has been theorized that *Snehana*decreases the sympathetic activity of the body, which may be one of the factors which may be decreasing the body fat. *Swedana*involves exposure of the body to external heat, which is believed to decrease the subcutaneous body fat. Stress is a common factor which is associated with increasing BMI as well as obesity which may be tackled by *Hridaydhara*, which leads to patient relaxation both mentally as well as physically. According to a published research on obese patients, *Basti* moderates the immune responses by controlling the pro-inflammatory cytokines, immunoglobulins and functional properties of T-cells. These alterations are associated with a reduction in the bodyweight.[15]

BMI does not discriminate between the fat mass and fat-free mass, which is an accepted indicator of the general health status. The robustness of BMI as an adequate obesity indicator is not proved in elderly individuals, as the fat-free mass decreases with age.[16] Waist circumference or abdominal girth helps in determining abdominal adiposity, which is a better indicator of risk to develop various metabolic diseases. By checking the correlation between BMI and abdominal circumference, it was proved that irrespective of the associated co-morbidity with CHF, HFRT significantly decreases general body mass as well as on abdominal adiposity, which correlated well in all subgroups of CHFpatients.

The study had a few limitations. The study assessment was done only after 30 days of HFRT, so long term effects of HFRT on the anthropometric parameters was not assessed. The study was of retrospective design, and so was dependent on the availability of patient data. Future research over a longer study period and with a prospective study design may be planned to generate more evidence for effect of HFRT on anthropometricmeasurements.

Conclusion

HFRT decreased BMI and abdominal circumference significantly in patients of CHF, irrespective of the presence of any other co-morbidity like HTN or DM. Both the anthropometric parameters correlated strongly in all the co-morbidity subsets of CHF patients.

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Impact of Comprehensive Diabetes Care (CDC) Management Program in Type II Diabetes Mellitus: A Retrospective Study

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Abstract: Globally, Diabetes mellitus (DM) prevalence has created menace, being a major culprit of increased mortality and morbidity and health care expenditures. India is the 2nd country with maximum number of diabetic patients, with an estimated prevalence of around 10%. Comprehensive Diabetes Care (CDC) is a combination of *Panchakarma* and Diet management. This study was conducted to evaluate the effect of CDC on glycosylated haemoglobin (HbA1c), body mass index (BMI), body weight, abdominal girth and dependency on conventional therapy in DM Patients. This retrospective study was conducted from July 2017 to January 2018, wherein the data of elderly male type 2 DM patients (HbA1c >6.5%) who attended *Madhavbaug clinics* in *Maharashtra*, India were identified. Data of patients who were administered CDC (60-75 minutes) with minimum 6 sittings over 90 days (± 15 days) were considered. Variables were compared between day 1 and day 90 of CDC. Out of 48 enrolled elderly male patients, 34 were included for analysis. CDC showed significant improvement in HbA1c from 8.27 ± 0.96to 7.1 ± 1.30; p=0.0001), BMI from 27.65 ± 3.20 to 25.91 ± 3.29, p< 0.0001), weight from 73.75 ± 10.76to 69.46 ±10.39, p<0.0001). Abdominal girth (from 100.0 ± 9.08 to 95.36 ± 9.10; p<0.0001), also showed significant reduction. Dependency on concomitant medicines was reduced, with number of patients on no concomitant medicines increasing from 3% to 15%. CDC and allopathy both are found to be efficacious; but CDC acts dually, by reducing HbA1c, as well as reducing dependency on allopathic medications.

Keywords: Comprehensive Diabetes Care, CDC, Panchakarma, HbA1C, BMI, DM, Alternative Medicine

1. Introduction

Diabetes mellitus type II (DM) prevalence has reached epidemic levels in global scale. International diabetes federation quotes that number of diabetics in 2030 will rise by estimated 200 million rise in number of cases, as compared to prevalence in 2011 [1]. This is far more concerning in India, where it is estimated that around 1/10th of the population is inflicted by DM, with significantlyhigh mortality rates [2, 3]. Historically, fastingblood sugar level >126 mg/dl and post-meal blood sugar level >140 mg/dl, which together constitute an oral glucose tolerance test is used for diagnosis of DM. Nowadays, glycosylated hemoglobin (HbA1c) is used for diagnosis of DM, as it depicts blood glucose levels over preceding 2-3 months. HbA1c levels >6.5% is diagnostic of DM, while levelslessthan 6.5 but more than 5.7% are dietary

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1. Introduction

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considered as prediabetics. Most of the guidelines suggest target HbA1c as ≤ 6.5% [4]. Plethora of complications of DM, grouped as macrovascular and microvascular, short term and long term, makes the disease more dangerous. Stroke, myocardial infarction, peripheral vascular disease are some of the macrovascular complications, while retinopathy, neuropathy and nephropathy are grouped under microvascular complications. However, major culprit for morbidity and mortality in diabetic patients is cardiovascular diseases (CVD) [5]. Foot ulcers, amputations are some of the after effects of diabetic neuropathy, while diabetic nephropathy is one of the major cause of morbidity and mortality in diabetic patients after CVD [6-9]. Diabetes is presently managed by advocating dietary corrections and regular physical exercise along with treatment with oral antidiabetic drugs/oral hypoglycemic agents (OADs). It is recommended to start OAD only when diet management and other measures are unable to bring down levels of HbA1c to < 6.5% after 2 months. The majority of the OADs act by either, reducing the intrinsic glucose production, increasing tissue uptake or increasing excretion. Sulphonylureas, thiazolidinedione, biguanides, etc. are some of the examples of conventional class ofantidiabetic drugs. When 1 OAD is unable to reduce the HbA1c below 7.5% or if baseline HbA1c is too high, it is recommended to use combination of OADs from different class [10]. But, major issues faced withthe use of OADs are a plethora of adverse effects which include hypoglycemia, pancreatitis, anemia, etc [11]. These adverse effects along with the increased cost of therapy has found to drastically reduce medication adherence in patients of DM [12]. Despite the availability of numerous classes of OADs and extensively laid down guidelines, number of cases ofDM are consistently increasing [12]. Thus an effective alternative therapy is needed, that will counteract these adverse effects of conventional medicines and increase patient adherence to medications for optimal outcome. OADs act by reducing blood sugar levels in the body. Various herbal drugs have shown similar effects in clinical studies, including significant reduction in HbA1c [13-15]. This makes Ayurveda a potential therapeutic alternative in patients of type 2 DM. Ayurvedic physicians advocate Panchakarma- a multi-step body detoxification process in the chronic phase of disease. *Panchakarma* and diet therapy is combined in Comprehensive Diabetes Care (CDC) Management Program. Three techniques are used in *Panchakarma* in CDC- *Snehana*i.e. oleation, *Swedana*i.e. passive heat therapy and *Basti* i.e. per rectal drug administration. *Panchakarma* is a well-known procedure for internal detoxification of the body [16-17]. Since reduction in quality of life, depression are associated with DM,we planned this retrospective study in elderlymale patients of type 2 DM, to assess the efficacy of CDC on various parameters like HbA1c, BMI, reduction in body weight, abdominal girth and reduction in dependency on conventional medications after completion of CDC

2. Subjects andMethods

Study Design

Retrospective record based study.

Study Site

Madhavbaug Clinics from all over Maharashtra

Study Period

July 2017 to January 2018.

Study Participants

Elderly male (>60 years), suffering from type 2 DM (HbA1c>6.5%),[10] who attended *Madhavbaug clinics* across *Maharashtra*.

Methodology

The data of patients who had been administered CDC with minimum 6 sittings over a span of 90 days (± 15 days) were considered for the study, out of the 6-8 sittings were done in the 1st month, and 1 sitting per month for next 2 months. These patients

were maintained on a diet plan of 800-1000 calories intake per day, according to patient medical records. The diet plan consisted of low carbohydrates, moderate proteins, and low fats. Cases were identified, and data was assessed from the records of *Madhavbaug clinics* in *Maharashtra*. The selection was based upon the availability of complete relevant baseline data (day 1 of CDC) and final day data (day 90 of CDC) of the patients. The information about prescribed concomitant medicines, if any, was also noted down. On day 1 of CDC, the patients had undergone HbA1c, weight, BMI, abdominal girth measurements as per guidelines [18]. This readings were considered as baseline reading. This process was repeated on day 90 of CDC to calculate the change from baseline reading. The BMI for day 1 and day 90 of the patients was calculated by checking the weight and the height from the medical data sheets ofpatients and using the formula: *weight in kilograms/ (height in meters)*^{2}. The dependency on standard medication was calculated both on day 1 and day 90 of CDC as the percentageof patients out of the total enrolled ones who required a conventional allopathic therapeutic agent during the study period of 90days.

The CDC is a 3-step procedure which was performed on the patients of type 2 DM after a light breakfast. One sitting of the procedure took 65-75 minutes, as described in table 1 [19-20]

Table 1. Study Treatment: Comprehensive Diabetes Care (CDC).

Step of CDC	Type of Therapy	Herbs used for therapy	Duration of Therapy
Snehana Swedana	Massage or external oleation (centripetal upper strokes on the body)	100 ml Azadirachta indica (neem) extract processed in sesame oil	25-30 minutes
	Passive heat therapy to the body	Dashmoola (group of ten herbal roots) with steam at <40	15-20 minutes + 3-4 minutes
Step of CDC	Type of Therapy	Herbs used for therapy	Duration of Therapy
		degrees Celsius)	of relaxation after procedure
Basti kadha	Per-rectal drug administration should be in body for > 15 minutes for maximum absorption	Mixture of 40% Cashmir (Gymnemasylvestre), 20% Dhanwantra (Barberis aristata) and 40% Yashimadhu (Glycyrrhiza glabra)	10 minutes

Statistical Analysis

Data were pooled and coded in Microsoft Excel spreadsheet. R Version 3.4.1 software was used to analyze the data. Categorical data were represented in the frequency formandcontinuousdatawerepresentedastheMean ± SD. Paired t-test was used to assess the difference between baseline values and 90thday after treatment. The histogram were used to represent thegraphs.

1. Results

Studypopulation:

A total of 48 patients' data was screened for inclusion in the study. However, based on the availability of data (Day 1 and Day 90) and the inclusion criteria, 34 patients were selected, and their data was considered for analysis. The present study involved a total of 34 male patients with more than 60 years age having a diabetic history and HbA1c ≥ 6.5. The mean age of the patients was 66.32 ± 4.86 years and mean height was 163.34 ± 6.53 cm. Clinical parameters compared between baseline values and after 90thday was as shown in Table 2. After 90 days of treatment there was significant reduction in the HbA1c (*P=0.0001; Figure 1*). There was significant reduction in weight (P<0.001; Figure 2), BMI (P<0.0001; Figure 3) and Abdomengirth (P<0.0001; Figure4)posttreatmentof90days.

Table 2. Comparison of clinical parameters between baseline values and 90th day

Variable (n=34)	Baseline	After 90 days	t statistic	p-value
HbA1c	8.27 ± 0.96	7.1 ± 1.30	4.71	0.0001
Weight (Kg)	73.75 ± 10.76	69.46 ± 10.39	10.961	< 0.0001
BMI	27.65 ± 3.20	25.91 ± 3.29	7.35	<0.0001
Abdomen girth (n=25)	100.0 ± 9.08	95.36 ± 9.10	8.1	<0.0001

HbA1c; Glycated haemoglobin, BMI; Body mass index

Table 3. Correlation of BMI and Abdomen girth with HbA1c at 1st day and after 90 days

Correlation between	Baseline		After 90days	
	R	p-value	r	p-value
BMI and HbA1c	0.05	0.76	0.07	0.69
Abdomen girth and HbA1c	-0.049	0.82	0.05	0.81

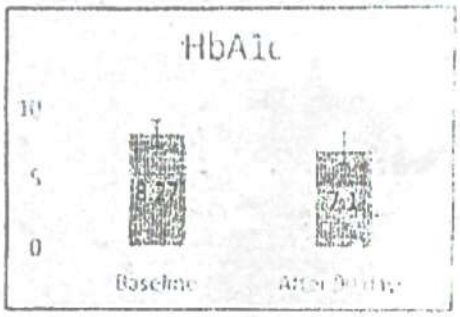

Figure 1. Comparison of HbA1c at baseline and after 90 days

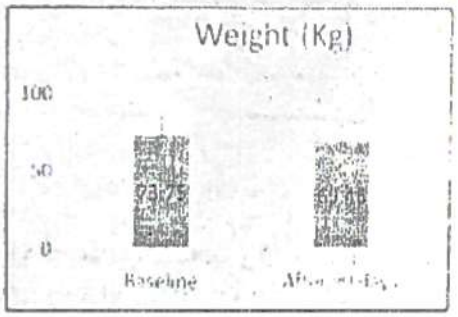

Figure 2. Comparison of weight of the patients at baseline and after 90 days

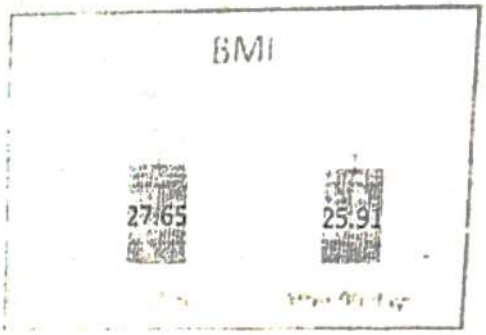

Figure 3. Comparison of BMI of the patients at baseline and after 90 days

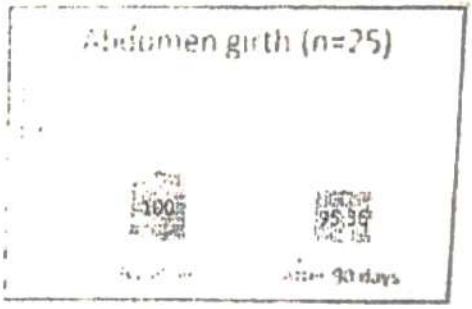

Figure 4. Comparison of abdomen girth of the patients at baseline and after 90 days

We also assessed the correlation between the BMI and HbA1c, abdominal girth and HbA1cb (table 3). There was a weak positive correlation between BMI and HbA1c (r= 0.05) on the 1st day of the treatment and it was not statistically significant (p=0.06), the same is shown in figure 5a. After 90 days of treatment we found nearly same positive relationship between BMI and HbA1c (r=0.07 p 0.70) which is shown in figure 5b.

We found a negative relationship between HbA1c and abdomen girth (r -0.049) on the 1st day of the treatment which was not statistically significant (p 0.82) (figure 5c). We found a weak positive relationship between them after the treatment (r=0.051) on day 90, and it was not statistically significant (p =0.81) (figure 5d).

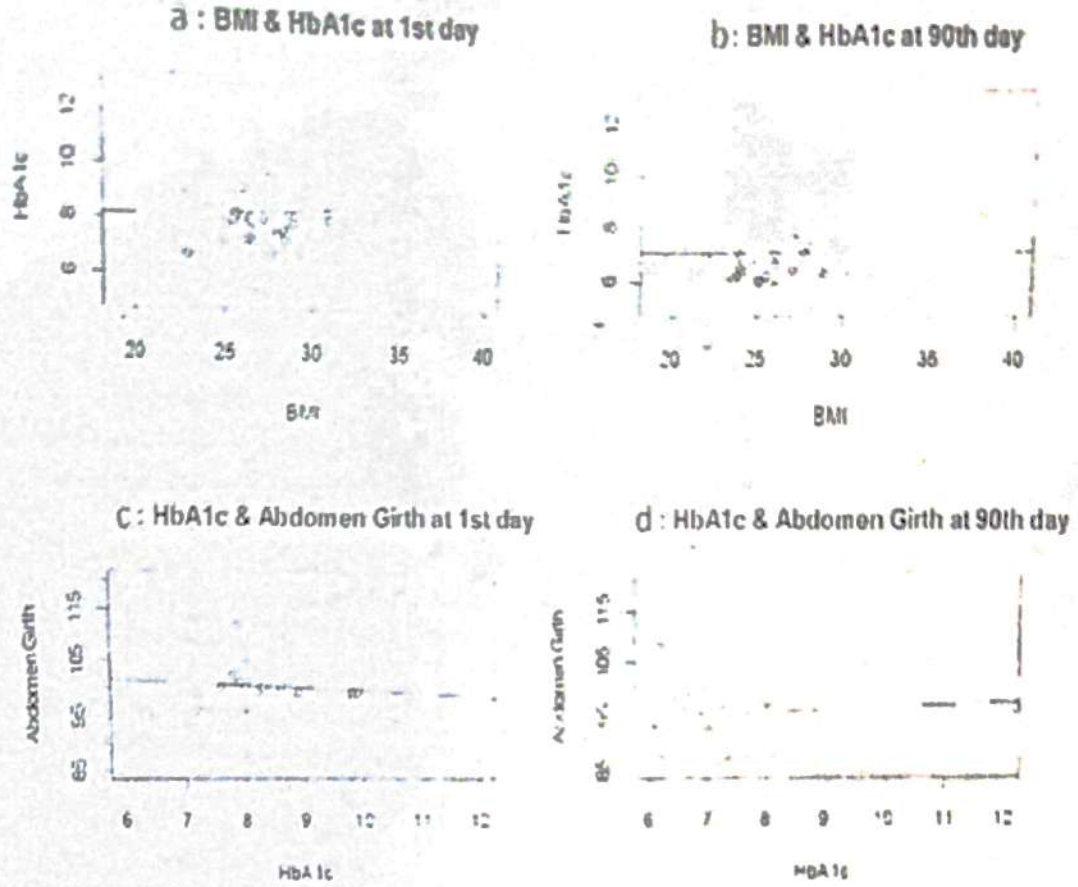

Figure 5. Correlation between BMI and HbA1c, abdomen girth and HbA1c

Allopathic medicines consumption on day 1 and after the 90th day of therapy were as shown in Table 4. Most of the enrolled subjects were treated with biguanides (58.82%), sulfonylurea (38.24%), nonsteroidal anti-inflammatory drugs (35.29%), statin (29.41%). All the subjects who were allopathic medicines before therapy was decreased after 90th day. However, the subjects with nonsteroidal anti-inflammatory drugs were not varied after the therapy. An illustration is given in figure 6.

Table 4. Consumption of allopathic medicines on the 1st and after 90 days

Medicine	Day 1	After 90 days
Sulfonylurea	13(38.24)	10(29.41)
Biguanide	20(58.82)	13(38.24)
Thiazolidinedione	4(11.76)	2(5.88)
DPP-4 inhibitor	8(23.53)	5(14.71)
Alpha-glucosidases inhibitors	5(14.71)	3(8.82)
Insulin	3(8.82)	3(8.82)
NSAID	12(35.29)	12(35.29)
Statin	10(29.41)	6(17.65)
ARB	8(23.53)	6(17.65)
Beta blocker	5(14.71)	2(5.88)
CCB	6(17.65)	5(14.71)
Antiplatelet	7(20.59)	7(20.59)
Nitrate	1(2.94)	1(2.94)
No medicine	1(2.94)	5(14.71)

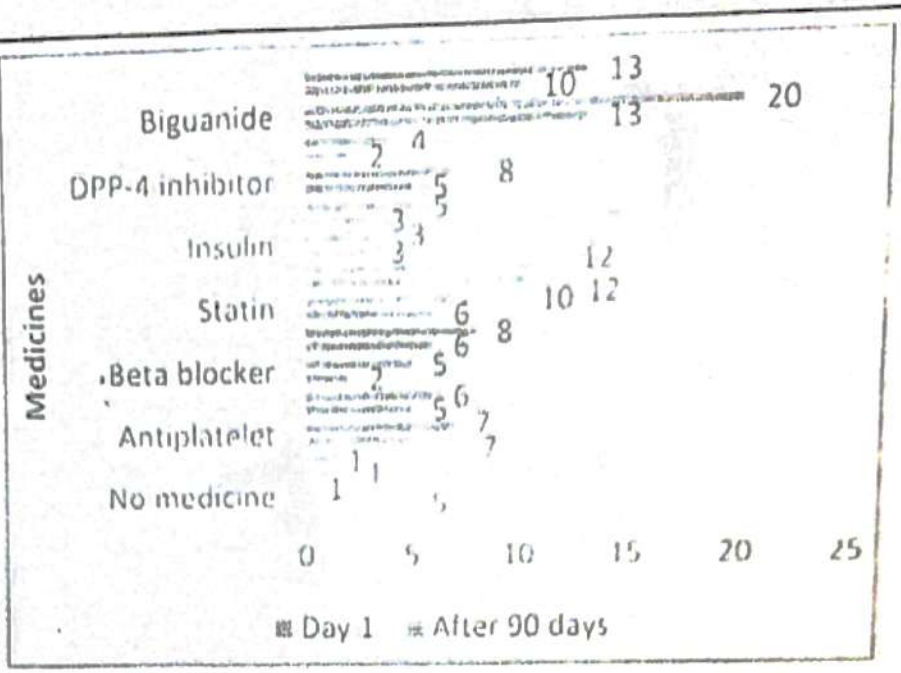

Figure 6. Comparison of consumption of allopathic medicine at 1st day and after 90 days

1. Discussion

Despite the availability of a plethora of therapeutic options for treatment of type II DM, its prevalence and contribution to global morbidity and mortality remains significantly high and is increasing continuously. Therefore, alternate therapeutic option to curb the menace of DM is the urgent necessity of current time. Conventionally used allopathic medicines in the treatment of type II DM act by reducing blood sugar levels. Ayurvedic medicines serves as a potential alternate therapeutic option for management of type II DM, since many herbal drugs have been found to significantly lower blood glucose levels in clinical studies. Ayurvedic physicians administer Panchakarma to the patients of DM [16]. Panchakarma along with diet therapy consisting of low carbohydrates and fats with moderate amount of proteins is administered in CDC. Probable mechanism, by which CDC might benefit patients with type II DM are:

1. Reducing glucose production in the liver by hampering sympathetic stimulation ongluconeogenesis,
2. Reducing the shear stress of vascular endothelium by promoting water loss via sweating. This may help in reducing vascular complications significantly [16].

In the present study, the CDC was found to significantly reduce ($p<0.001$) HbA1c, BMI, body weight, abdominal girth, at the end of study period i.e. 90th day. Another crucial finding of our study was that there was significant reduction in patients' dependency on conventional allopathic antidiabetic medications at the end of the studyperiod.

HbA1c value is one of the most crucial parameter in diabetic patients as it echoes blood sugar level control over preceding 2-3 months [4]. Another important feature of HbA1c is its prognosticator value in type 2 DM, since it has been found that morbidity and mortality is directly related to sustained increased HbA1c [21]. Thus it can be anticipated from the findings of our study that CDC carries a good prognosis in diabetic patients as it significantly reduces HbA1c. Obesity and sedentary lifestyle contribute to development of DM which is indicated by increased BMI [22]. Apart from DM, high BMI has epidemiological linkage with many chronic diseases like HTN and other CVDs [23]. Sustained

control of blood sugar levels is the utmost important factor in diabetic patients, since it has been established that poor blood sugar level control is associated with increased incidence of complications [24]. CDC can help in reducing complications of DM since it showed sustained reduction in all parameters like HbA1c, BMI, body weight,etc.

Another major issue with the use of conventional drugs is increased cost of therapy along with increased incidence of adverse effects associated with use of these drugs [25]. Hence, we assessed the effect of CDC on dependency on conventional medications. In our present study, we found that there was an overall reduction in dependency of patients on conventional medications at the end of the study period. Also, the number of patients who went off the conventional drugs increased at the end of 90th day.

In order to generalize the findings of our study to the larger population, we recommend conduction of similar studies with dual arms, to allow direct comparison with conventional therapy, prospective design, and long follow up period with larger samplesize.

1. Conclusion

Major parameters of the body deranged in DM are BMI, body weight, abdominal girth all of which worsen complication rate. Although conventional correct these parameters to some extent cost of therapy and adverse effects offset their beneficial effects and decrease patient compliance. CDC corrected all these parameters effectively and also reduced dependency on conventional drugs, all of which have positive contributory effect on enhancing patient compliance. Thus it is safe to conclude that CDC canbeconsidered as effective and safe therapeutic option for treatment of DM.

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The authors thank the study participants and their families, without whom this study would not have been accomplished.

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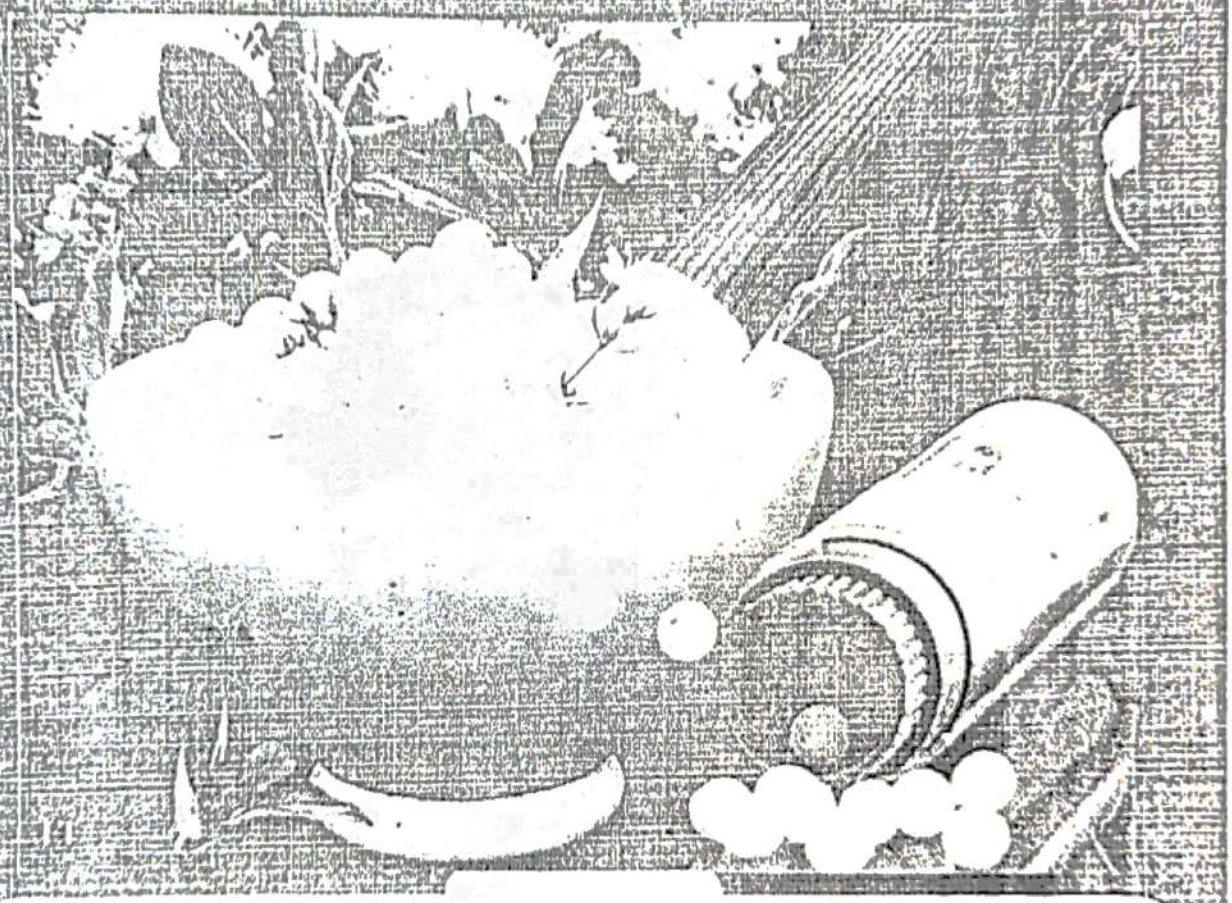

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IMPACT OF COMPREHENSIVE DIABETES CARE (CDC) MANAGEMENT PROGRAM IN TYPE II DIABETIC OBESE PATIENTS: AN OBSERVATIONAL STUDY

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ABSTRACT

Context: Diabetes mellitus (DM) contributes to a major chunk of morbidity, mortality, and healthcare cost on a global level. The prevalence of DM is rising alarmingly, worldwide and India Comprehensive Diabetes Care (CDC) is a combination of *Panchakarma* and diet management.

Aims: This study was conducted to evaluate the effect of CDC on Glycosylated hemoglobin (HbA1c), body mass index (BMI), body weight, abdominal girth and dependency on conventional therapy in DM Patients.

Setting and Design: This observational study was conducted in July 2017, wherein the data of obese Type II DM patients (HbA1c >6.5%) who attended out-patient departments (OPDs) at *Madhavbaug* clinics in Maharashtra, India were identified.

Materials and Methods: Data of patients who were administered CDC (60-75 minutes) with minimum 6 sittings over 90 days (± 15 days) were considered. Variables were compared between day 1 and day 90 of CDC.

Results: Out of 27 patients, 22 were included for analysis, out of which 10 were males while 12 females. CDC showed significant improvement in HbA1c 1.1% (from 8.80±0.93 to 6.98±1.73; p<0.001), BMI by 2.66 (from 33.79±3.80 to 31.13±3.91, p<0.001), weight by 6.56 kg (from 83.67 ± 11.28 to 77.11 ± 12.27, p<0.001). Abdominal girth (from 104.34 ± 9.74 to 96.97 ± 11.93; p<0.001), also showed significant reduction. Dependency on concomitant medicines was reduced, with the number of patients on no concomitant medicines increasing from 27% to 41%.

Conclusion: Comprehensive Diabetes Care Management Program found to be

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efficacious; by reducing HbA1c, as well as reducing dependency on allopathic medications.

KEYWORDS: Comprehensive Diabetes Care, CDC, *Panchakarma*, Glycosylated HB, HbA1C, BMI, DM, Alternative Medicine.

INTRODUCTIONDiabetes mellitus (DM) contributes to a major chunk of morbidity, mortality, and health care cost on a global level. The prevalence of DM is rising alarmingly, worldwide.[1] India is only 2nd to China, in terms of prevalence of DM, with a prevalence rate of around 10%; i.e. every 10th adult in India is suffering from DM.[2] According to WHO report, about 30 people die per 1 Lac population in India, due to diabeticcomplications.[3]

Conventionally DM is diagnosed based on blood glucose/sugar levels (BSL), fasting levels more than or equal to 126 mg/dl and post prandial levels more than or equal to 140 mg/dl is considered as a DM. In recent decade diagnosis is also done by measuring glycosylated hemoglobin (HbA1c), since it reflects blood sugar control over the past 2-3 months.

HbA1c levels more than 6.5% is considered as DM, 5.7% to 6.4% as a borderline case/ predlabetes, and less than 5.7% as normal. Target HbA1c for treatment strategies are taken as below 6.5%.[4]

DM is dreaded due to its complications, which are short term and long term, macrovascular and microvascular. Macrovascular complications include myocardial infarction, coronary artery disease, stroke, cerebrovascular disease, peripheral vascular disease, etc. Microvascular complications include retinopathy, neuropathy, nephropathy. Out of these, cardiovascular complications are leading cause of morbidity and mortality in diabetic patients.[5] Diabetic neuropathy may manifest as foot ulcers, sexual dysfunction in young males, amputation, etc.[6,7] Amongst microvascular complications, nephropathy is leading cause of morbidityand of the disease, while herbal drugs are preferred inmortality in diabetic patients.[8] The prevalence of retinopathy in diabetics is also increasing these days.[9] It has been postulated from findings of various epidemiological studies that certain cancers are more common in diabetics like, cancers of breast, kidney, colo-rectal, bladder,etc.[10,11]

The current management plan includes lifestyle modification, including dietary modifications and physical exercise on a daily basis plus pharmacological management (oral antidiabetic drugs).

Antidiabetic drugs/oral hypoglycemic agents (OHA) should be initiated only if a lifestyle modification fails to reduce HbA1c below 6.5% after 2 months. Major class of OHAs includes Biguanides (Metformin), Thiazolidinediones (Pioglitazone), Sulphonylureas (Glimepiride), Dipeptidyl peptidase-4

(DPP-4) inhibitors like Teneligpiltin, Sodium glucose cotransporter-2 inhibitors (canagliflozin). All these drugs act either, by reducing blood glucose via increasing tissue uptake, decreasing endogenous glucose production, preventing breakdown of incretins, etc. Guidelines suggest that, if baseline HbA1c is > 9% or it remains >7.5% despite 1 OHA, then combination of 2 OHAs should begiven.[12]

But, these drugs are associated with a wide variety of adverse effects like hypoglycemia (almost all classes), megaloblastic anemia (biguanides), pancreatitis, upper respiratory tract infections (gliptins), ketoacidosis, bone fractures (SGLT2 inhibitors), lipodystrophy at injection site (insulin), C cell tumour of thyroid (GLP1 agonist), etc.[13]In a multicentric study on diabetic patients, it was found that adherence of patients to antidiabetic drugs was only 58%. The investigators of the study attributed this low adherence to cost of therapy, adverse effects of medications. Also, despite numerous guidelines for DM, its prevalence is rising continuously.[14] Thus, it is the need of the hour to explore alternate forms of antidiabetic therapy, which can ameliorate the factors associated with low adherence to allopathic anti diabetic drugs.

The therapeutic benefit of allopathic antidiabetic drugs in diabetes is due to their blood glucose lowering action. Several studies have shown similar effects, with significant reduction in Glycosylated Hemoglobin (HbA1c), Fasting and Post Prandial Blood Glucose (FBG, PPBG) levels and lipids, by using herbal drugs, which serve as interesting potential targets for newer therapeutic options for treatment of DM.[15,16,17]

Panchakarma is multi-step internal purification process. *Panchkarma*therapy in Ayurveda practice is administered in chronic phase

acute phase. Comprehensive Diabetes Care (CDC) combines *Panchakarma* and diet management. Under this management program, *Panchakarma* is advocated through threetechniques- *Snehana*i.e. oleation, *Swedana*i.e. passive heat therapy and *Basti* i.e. per rectal drug administration. *Panchakarma* techniques are already well established in literature, as detoxifying procedures.[18,19]DM is found to be linked with depression, reduction in quality of life, etc.[20]Hence, we planned an Observational study to investigate the efficacy of the CDC, as add-on therapy to standard anti-diabetic therapy in patients with DM. We evaluated the effect of CDC on HbA1c, weight, body mass index (BMI), abdominal girth, and dependency of these diabetic patients on standard conventional oral antidi abetic medications

Since, numerous factors play a role in causation, progression of DM, its

management should be multi-pronged. Given the fact that Ayurveda may serve as potent alternative therapy, its efficacy in DM should be tested.[15,17,21] Hence, we planned this observational study to investigate the effect of the CDC, as add on therapy to standard anti-diabetic therapy in obese patients with type II diabetes mellitus. We evaluated the effect of CDC on HbA1c, body mass index (BMI), body weight, dependency on oral hypoglycemic drugs/ agents, and abdominal girth.

MATERIALS AND METHODS

This was an Observational study conducted between July 2017, wherein we identified the data of obese patients suffering from type II DM (HbA1c ≥ 6.5%, BMI ≥ 30) [14,5] of either gender and any age, and who had attended the out-patient departments (OPDs) at multiple *Madhavbaug*clinics located in various cities of Maharashtra, India. The data of patients who had been administered CDC with minimum 6 sittings over a span of 90 days (± 15 days) were considered for the study, out of which 4 sittings were done in the 1st month, and 1 sitting per month for next 2 months. These patients were maintained on a diet plan of 800-1000 calories intake per day, according to patient medical records. The diet plan consisted of low carbohydrates, moderate proteins, and low fats. Cases were identified, and data were assessed from the records of *Madhavbaug*clinics in Maharashtra. The selection was based upon the availability of complete relevant baseline data (day 1 of CDC) and final day data (day 90 of CDC) of the patients. The information about prescribed concomitant medicines, if any, was also noteddown.

The CDC is a 3-step procedure which was performed on the patients of type II DM after a lightbreakfast. One sitting of the proceduretook 65-75 minutes, as described in table 1.[19,22]

Table 1: Study Treatment: Comprehensive Diabetes Care (CDC)

Step of CDC	Type of Therapy	Herbs used for therapy	Duration of Therapy
Snehana	Massage or external oleation (centripetal upper strokes on the body)	100 ml *Azadirechtaindica*(neem) extract processed in sesame oil	20 minutes
Swedana	Passive heat therapy to the body	*Dashmoola*(group of ten herbal roots) with steam at ≤40 degrees Celsius)	15-20 minutes + 3-4 minutes of relaxation after procedure
Basti kadha	Per-rectal drug administration should be in body for ≥ 15 minutes for maximum absorption	Mixture of 40% *Gudmar*(*Gymnemasylvestre*), 20% *Daruharidra* (*Berberis aristate*) and 40% *Yashtimadhu* (*Glycyrrhiza glabra*)	10 minutes

On day 1 of CDC, the patients had undergone HbA1c, weight, BMI, abdominal girth measurements as per guidelines.[4] This reading was considered as baseline reading. This process was repeated on day

90 of CDC to calculate the change from baseline reading. The BMI for day 1 and day 90 of the patients was calculated by checking the weight and the height from the medical data sheets of patients and using the formula: weight in kilograms/ (height in meters)^2. The dependency on standard medication was calculated both on day 1 and day 90 of CDC as the percentage of patients out of the total enrolled ones who required a conventional allopathic therapeutic agent during the study period of 90days.

Statistical analysis

Data were pooled and entered in Microsoft Excel spreadsheet. R Version 3.4.1 software was used to analyze the data. Categorical data were represented in the numeric form and continuous data were presented as the Mean ± SD. The Paired t-test was used to assess the difference between baseline values and 90thday after the treatment. Box plot, histograms and scatter plot were used to represent thegraphs.

RESULTS

Study population

A total of 27 patients' data was screened for inclusion in the study. However, based on the availability of data (Day 1 and Day 90) and the inclusion criteria, 22 patients were selected, and their data were considered for analysis.

Figure 1: Treatment Plan of Comprehensive Diabetes Care Management

The study comprised of 22 type II diabetic obese patients, among them10 (45.45 %) were men and 12 (54.55 %) were female. The mean age of the study patients was 48 ± 12.13 years. A significant improvement in weight, (77.11±12.27vs.83.67±11.28;P<0.001),BMI(31.13±3.91vs.33.79±3.80;P<0.001),HbA1c(6.98±1.73 vs. 8.80 ± 0.93; P = 0.0002) and abdomen girth (96.97 ± 11.93 vs. 104.34 ± 9.74; P < 0.001) were observed in diabetic obese patients after the treatment (90 days) than before treatment (baseline) (Table 2; Figure

2).Table 2: Comparison of clinical parameters between baseline values and 90th day of the treatment

Variable	Baseline (Day 1)	After 90 days	Difference	P value
Weight	83.67 ± 11.28	77.11 ± 12.27	6.56	<0.001
BMI	33.79 ± 3.80	31.13 ± 3.91	2.66	<0.001
HbA1c	8.80 ± 0.93	6.98 ± 1.73	1.1	0.0002
Abdomen Girth (n=19)	104.34 ± 9.74	96.97 ± 11.93	7.37	<0.001

BMI, Body Mass Index; HbA1c, Glycosylated hemoglobin

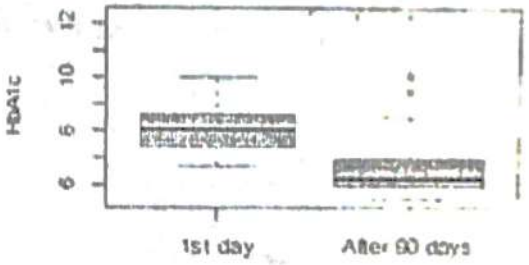
Fig 2.1: Comparison of Weight

Weight on 1st day and after 90 days

Fig 2.2: Comparison of BMI

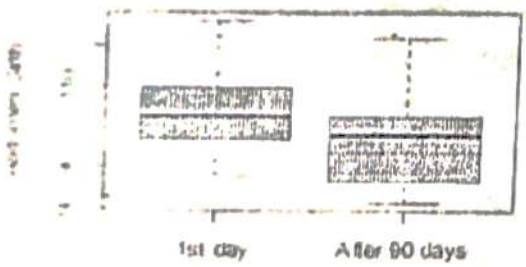
1st day and after 90 days

Fig 2.3: Comparison of HbA1c



HbA1c on 1st day and after 90 days

Fig 2.4: Comparison of Abdomen Girth



Abdomen Girth on 1st day and after 90 days

Figure 2: Comparison of clinical parameters between baseline values and 90th day (N=22)

Most of the type II diabetic obese patients were treated with beta blockers (13.64 %), nonsteroidal anti- inflammatory drugs (13.64 %), biguanides (54.55 %) and sulfonylureas (36.36). While, the patients depending only on biguanides (36.36 %) showed marked decrease after the treatment i.e., 90 days. The patients with the absence of medication history (40.91 %) were also improved after treatment (Table 3; Figure3).

Table 3: Consumption of allopathic medicines on days 1 and 90

Medicine	Baseline	After 90 days
Alpha-glucosidases inhibitors	1 (4.55)	1 (4.55)
DPP-4 inhibitor	3 (13.64)	1 (4.55)
Thiazolidinedione	1 (4.55)	1 (4.55)
Biguanide	12 (54.55)	8 (36.36)
Sulfonylurea	8 (36.36)	8 (36.36)
Antiplatelet	1 (4.55)	1 (4.55)
CCB	1 (4.55)	1 (4.55)
Beta blocker	3 (13.64)	3 (13.64)
ARB	2 (9.09)	1 (4.55)
Statin	1 (4.55)	1 (4.55)
NSAID	3 (13.64)	3 (13.64)
No medicine	6 (27.27)	9 (40.91)

NSAID, Nonsteroidal anti-inflammatory drugs; ARB, Angiotensin II receptor blockers; CCB, Calcium channel blockers; DPP-4 inhibitor, Dipeptidyl peptidase-4

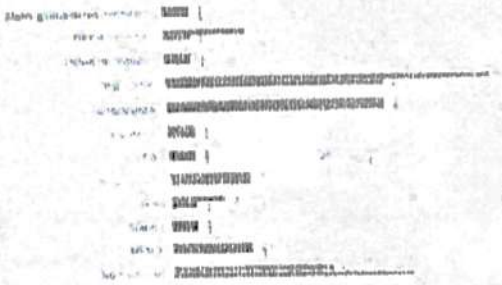


Figure 3: Consumption of allopathy medicines at days 1 and 90 days (N = 22)

NSAID, Nonsteroidal anti-inflammatory drugs; ARB, Angiotensin II receptor blockers; CCB, Calcium channel blockers; DPP-4 inhibitor, Dipeptidyl peptidase-4

The levels of HbA1c were significantly correlated with the BMI after 90 days of treatment ($r = 0.504$; $P = 0.016$) when compared with baseline values ($r = 0.39$; $P = 0.071$). (Table 4; Figure 4).

Table 4: Correlation of BMI and abdominal girth with HbA1c at 1st day and after 90 days of treatment

Correlation between	Baseline		After 90 days	
	r	P value	r	P value
HbA1c & BMI	0.39	0.071	0.504	0.016

BMI, Body Mass Index; HbA1c, Glycosylated haemoglobin

Fig4.1: BMI&HbA1cat1stday

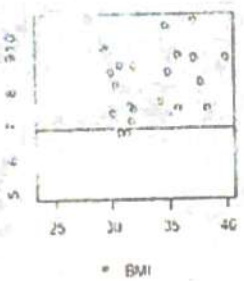
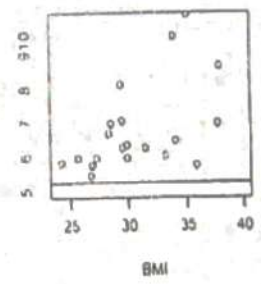


Fig4.2:BMI&HbA1cat90thday



BMI, Body Mass Index; HbA1c, Glycosylated hemoglobin

BMI, Body Mass Index; HbA1c, Glycosylated hemoglobin

Figure 4: Correlation of BMI and abdominal girth with HbA1c at 1st day and after 90 days of treatment

DISCUSSIONAlthough there are numerous treatment choices available for treatment of type II DM management, it is still one of the commonest culprits of morbidity and mortality globally. Thus, it is the need of the hour to explore novel therapeutic alternatives for the management of type II DM. Traditional class of antidiabetic drugs has

therapeutic benefit in DM of lowering bloodsugar levels. Similar property has been found in various herbal drugs, thus making Ayurveda a potent and viable alternative to standard therapy in the management of type II DM. Panchakarma is administered as add on therapy for DM management, by Ayurveda physicians.[123] C D C combines *Panchakarma* with Low carb moderate protein and low fat diet. CDC acts by reducing sympatheticstress , reduced sympathetic action lowers hepatic glucose production, which can be helpful to reduce blood sugar levels *Swedanais* helps by it inducing sweating and reduces excess of sodium and water, and this comprehensively helps to improve vascular health of DM patients to keep them away from probable vascular complications.[124]In pursuit of analyzing the efficacy of CDC in type II DM, we found that it showed significant (very high statistical significance) improvement in HbA1c, weight, BMI, abdominal girth at the 90thday of the whole procedure. Most importantly, we found that CDC noticeably reduced patient's dependency on standard allopathic medication at the end of 90 days, may be of therapy

The HbA1c levels are more important in diabetic patients since it reflects the average blood sugar control over the past 1-2 months.[125]Importance of HbA1c lies in the fact that, it is an independent predictor of mortality and morbidity in patients with type II DM. This has been corroborated in a prospective study done on diabetic patients, that cardiovascular complication like stroke was significantly lower in patients with an optimal reduction in HbA1c. It was found in large study- UKPDS study on diabetic patients, that reduction in HbA1c by 1% led to reduction of heart failure, heart attack, stroke, amputation and overall morbidity and mortality in diabetic patients.[125] Hence, significant reduction in HbA1c after CDC in our study indicates favorable prognosis in DM relatedmorbidity.

High BMI is considered to be one of the major risk factor for development of DM in normal subjects. It signifies sedentary lifestyle and obesity.[126] Also, it has been found that BMI is positively associated with type II diabetes mellitus, hypertension, cardiovascular diseases and other chronic diseases.[127] Uncontrolled DM frequently leads to the development of complications, hence various management plans across the globe have targeted sustained blood sugar control in patients with DM, to prevent the occurrence of such complications.[81] In the

present study, CDC significantly reduced HbA1c, BMI, abdominal girth, body weight. Thus CDC can play significant role in preventing the development of complications in patients with DM, thereby reducing morbidity andmortality. In developing economy like India, the dependency of diabetic patients on allopathic medicines escalates the cost of healthcare to troublesome levels. Plethora of adverse effects of these drugs complicates the scenario, furthermore.[29] Keeping this in mind, we analyzed changes in patient's dependency on allopathic medication by CDC. There was significant reduction in dependency on almost all the class of antidiabetic drugs (oral hypoglycemic agents), at the end of 90 days, with an increase in the number of patients who went off the allopathic drugs.

One limitation of the study was that, it had only one arm, thus we were not able to compare CDC findings with that of standard therapy alone. The findings of the present study can be generalized only after a comparison with the findings of other such studies with probably prospective design, larger sample size, and more follow up period. This will help in identifying long term outcomes of CDC in the management of type II DM.

CONCLUSION

There was significant improvement in HbA1c after CDC. Also, there was significant reduction in patient's dependency on allopathic medications. Significant reduction in HbA1c, coupled with reduction in BMI, body weight, abdominal girth after CDC indicates a better prognosis in patients with type II DM. Hence, CDC may serve as a potent and viable alternative to standard allopathic treatment of type II DM.

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Impact of Comprehensive Diabetes Care on Glycaemic Control with Reduction in Dependency of Oral Hypoglycaemic Medicines in Diabetic Patients: A Retrospective Study

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Abstract

Although multiple new drugs are coming out in the market, India has the 2nd highest number of diabetics in the world. The aim of this study was to evaluate effects of Comprehensive Diabetes Care (CDC) on Glycosylated haemoglobin (HbA1c) and metabolic parameters in pre-obese diabetic patients. In this retrospective study, data of pre-obese DM patients who had received 6 CDC sittings over 90 days in the out-patient departments (OPDs) at *Madhavbaug*clinics was collected between May 2013 to April 2018. Demographic and co-morbidity details were noted. HbA1c, body mass index (BMI), abdominal girth, systolic and diastolic blood pressure (SBP, DBP), dependency on medications were assessed on days 1 and 90 of CDC. The patients followed a specific low-caloric diet plan during the study. 89 participants, (52 males; 37 females) were enrolled. Mean HbA1c measured at day 90 was significantly lower than that on day 1(6.86 ± 1.24 vs 9.02 ± 1.79, p<0.001). Mean BMI was significantly reduced on day 90 when compared to baseline (25.39 ± 1.53 vs 27.24 ± 1.33, p<0.001). Abdominal girth was significantly decreased on day 90 compared to baseline (91.64 ± 6.26 vs 97.12 ± 7.03, p<0.001). SBP (122.83 ± 13.56vs 131.60 ± 16.10, p<0.001) and DBP (77.02 ± 6.81 vs 81.75 ± 9.43, p<0.001) were also significantly decreased after 90 days. Dependency onconcomitant medicines wasreduced.

Glycaemic control and metabolic parameters significantly improved after 90-day CDC treatment. Reduction in blood pressure and intake of concomitant medications were also noted.

Keywords

Comprehensive diabetes care, CDC, Panchakarma, Diabetes mellitus, HbA1c, Body mass index, Ayurveda, Alternativemedicine

Introduction

Diabetes mellitus (DM) is a known global health-hazard, affecting millions of people worldwide. According to World Health Organization (WHO), the number of diabetic patients has increased from

108 million in 1980 to a staggering 422 million in 2014. (WHO, 2018) The International Diabetes Federation (IDF) has mentioned that about 1 in 11 adults belonging to the age group of 20 years to 79 years are suffering from DM worldwide. (International Diabetes Federation, 2018) It is interesting to note that 3/4th ofthe patients suffering from DM worldwide belong to the low-income and middle-income countries, and India is one of them. (Tripathy*et al.*, 2017) It is estimated that in 2015, India had more than 69 million DM patients, which is considered to bethesecond highest number in the world, next to only China. (International Diabetes Federation, 2018) The DM prevalence is expected to double after 20 years, because of the elevating age-expectancy, increasing obesity as well as the increased exposure of population to various risk factors. The patients suffering from DM also are at a risk of developing various dangerous complications like retinopathy, neuropathy and various microvascular and macrovascular diseases. Current management of DM aims to render a good glycaemic control and prevent the development or progression of complications. There are multiple treatment modalities for the management of DM which include parenteral insulin preparations and oral hypoglycaemic agents like metformin, sulfonylureas, sodium glucose transport inhibitors, thiazolidinediones. Despite the presence of these multiple classes of drugs, the prevalence of DM is on an upswing. Literature reveals glycated haemoglobin (HbA1c), the main indicator of long term diabetes control, is in the normal range in only 50% of the DM patients (Del Cañizo- Gómez and Moreira-Andrés, 2004) The various drugs used for the management of DM are also associated with multiple adverse effects. (Goodman *et al.*, 2011) Hence, there is a need for new or alternative therapeutic modalities for the treatment of DM

Ayurveda is a commonly practiced ancient art of alternative medicine in India, which simply means 'Science of Life' The main purpose of *Ayurveda* is to keep an equilibrium between the physiological and structural entities, which indicates good health. (AYUSH, 2007) The description of DM (*Madhumeha*) is present in the ancient Ayurvedic literature, indicating that the knowledge of the disease was present with the Ayurvedic physicians. (Upadhyay and Kamla, 1984) The Ayurvedic physicians are using a multi-faceted management approach to treat DM in India, which include the usage of *Panchakarma*, herbal preparations, yoga and breathing exercises along with diet modifications. Comprehensive diabetes care program (CDC) is one such alternative treatment modality, which includes a combination of herbal treatment with *Panchakarma* and allied therapies. The techniques used in *panchakarma* are *Snehana*(Centripetal oleation), *Swedana*(Thermal vasodilation) and *Basti* (per rectal drug administration), which are known to remove toxins from the body. (Mishra, 2003; Uebaba*et al.*, 2008) However, there is a paucityof literature which indicates that this alternative treatment modality is efficient in controllingDM.

Hence, a retrospective study was planned to assess the effect of CDC in the treatment of patients with DM

HbA1C, the main indicator of DM control, was the primary outcome measure in this study. The body mass index (BMI) appears to have a direct

relationship with the relative risk of several chronic conditions, including DM, hypertension, coronary heart disease, and cholelithiasis (Willett *et al.*, 1999) Therefore, those DM patients who had a pre-obese BMI range were enrolled to assess the effect of CDC onvarious metabolic parameters like BMI, weight and abdominal girth along with the effect onHbA1c.

Subjects and Methods

This was a retrospective study conducted between May 2013 to April 2018, wherein we identified the data of patients who had attended the out-patient departments (OPDs) at multiple *Madhavbaug*clinics located in various cities of Maharashtra in India and were suffering from DM. The data of patients having an HbA1c level above 7% were included in the study. The other main inclusion criterion was that the included patients must have a baseline BMI between 25 $kg/m^2$to 29.9 kg/m^2, as the study intended to include pre-obese patients with DM. The patients were administered CDC once a week in the 1stmonth, followed by once a month in the next two months. Data of only those patients were included who had received the scheduled 6 sitting in a span of 90 days. Cases were identified, and data were assessed from the records of *Madhavbaug*clinics in Maharashtra The selection was based upon the availability of complete relevant baseline data (day 1 of CDC) and final day data (day 90 of CDC) of the patients. The information about prescribed concomitant allopathic medicines was also noted down. The CDC is a 3-step procedure which lasts for about an hour per sitting. The details of the regimen have been mentioned in table 1. Various procedures of the CDC regimen were carried out on a single day for one singlepatient.

On day 1 of CDC, the fasting serum HbA1C of the patients was assessed along with the assessment the weight, height and the abdominal girth. The details of the concomitant anti-hyperglycaemic treatment were also noted down on day 1. These details were again noted down on day 90 of CDC, for comparison with the baseline (day 1) findings. The BMI for day 1 and day 90 of the patients was calculated by checking the weight and the height from the medical data sheets of patients and using the formula: *weight in kilograms/(height in meters)*^{2}. Diabetic diet plan, based on the principle of low-calorie and low-carbohydrate diet, was followed by the patients throughout the 90 days study period.Data were pooled and coded in Microsoft Excel spreadsheet. R Version 3.4.1 software was used to analyze the data. Categorical data were expressed in the form of frequency (%) and continuous data were expressed in the form of Mean ± SD. The paired t-test was used to assess the statistical difference between baseline and 90th day values. The correlation between abdominal girth and HbA1c as well as between abdominal girth and BMI was calculated using Pearson correlation coefficient. Scatter plot and bar graphs were used to represent the results.

Results and Discussion

The study comprised of 89 participants with striking male predominance (58.43%). Baseline characteristics of the study participants were as given in Table 2. Nearly three-fourth of the study participants had past-history of diabetes mellitus, while the second highest morbidity history

reported was hypertension (43.82%). The major baseline characteristics are mentioned in table2

The comparison of clinical parameters between baseline values and those noted at 90th day are given in Table 3. The BMI was significantly reduced ($P < 0.001$) along with the measured abdominal girth ($P < 0.001$). HbA1c ($P < 0.001$), systolic blood pressure ($P < 0.001$) and diastolic blood pressure ($P < 0.001$) were also found to be significantly reduced after 90 days of treatment as compared to the respective mean baseline values.Figures
2 to 5 represent the graphical representation of the comparison between baseline and 90th day mean parameters. The correlation between abdominal girth and HbA1c, abdominal girth and BMI as well as between HbA1c and BMI was calculated using Pearson correlation coefficient (table 4). There was a weak positive correlation between abdominal girth and HbA1c (r=0.018) on the 1st day of the treatment and it was not statistically significant (p=0.87), the same is shown in figure 5.1. After 90 days of treatment we found stronger positive relationship between abdominal girth and HbA1c which was approaching to statistical significance (r=0.18, p=0.084) as showed in figure5.2.

There was a positive correlation between abdominal girth and BMI (r=0.28) on the 1st day of the treatment and it was statistically significant (p=0.007), the same is shown in figure 5.3. After 90 days of treatment we found a highly significant positive relationship between abdominal girth and BMI (r=0.48, p<0.001) same is shown in figure 5.4.
The study participants were on various concomitant medications for DM as well as other co-morbidities. We compared the consumption of the allopathy medications by the participants, on day 90 and day 1, to check whether there was any reduction in the dependency on these standard medications by CDC. Table 5/Figure 6 gives the comparison between the consumption of allopathic medicines at day 1 and day90.

Ayurvedic practitioners have been treating DM using various preparations like *Chandraprabhavati*since a long time. It is hypothesized that Ayurvedic medicines may be acting via various potential pancreatic and extra-pancreatic effects. Comprehensive diabetes care (CDC) is one such Ayurvedic intervention which consists of 3 main components; *Snehana*(Centripetal oleation), *Swedana*(Thermal vasodilatation) and *Basti* (per rectal drugadministration).

We assessed the effects of this treatment technique on HbA1c, weight, BMI and abdominal girth. All these parameters were significantly reduced in the patients on CDC management, at the end of 90 days. HbA1c is a significant indicator of long-term glycaemic control in DM patients, with the capability to reflect the cumulative glycaemic control in the previous two to three months. (Sherwani *et al.*, 2016) Therefore, HbA1c was our primary parameter and the reduction in HbA1c by CDC gives a good evidence. Literature search revealed that even a mildly increased BMI can increase the chances of developing complications in DM. (Gray *et al.*, 2015) the positive effect of CDC in decreasing BMI can help prevent the potential complications too. Research articles have mentioned that abdominal girth is the best

parameter to assess adiposity and predict the outcome of DM. (Ghosh and Bandyopadhyay, 2012) Hence, we measured the effect of CDC over abdominal girth, which revealed positive outcome. We also found a strong positive correlation between BMI and HbA1c at the end of CDC treatment. This goes in sync with a research by Gummesson*et al.*, which mentioned that weight loss in the overweight population is consistently associated with HbA1c, in a dose dependent manner (Gummesson*et al.*, 2017) We also found a reduction in the patients who were on these allopathic drugs. This indicates that CDC may be one of the factors associated with the decrease in load of medications in DM patients, and also helps them in avoiding the potential adverse effects of the allopathic medications.

Table.1 Study Treatment: Comprehensive Diabetes Care (CDC)

Table.1 Study Treatment: Comprehensive Diabetes Care (CDC)

Step of CDC	Type of Therapy	Herbs used for therapy	Durationof Therapy
Snehana	Massage or external oleation (centripetal upper strokes on the body)	100 ml *Azadirachtamukhcm*(neem) extract processed in sesame oil	20 minutes
Swedana	Passive heat therapy to the body	*Dashamoola*(group of ten herbal roots) with steam at <40 degrees Celsius)	15-20 minutes + 3-4 minutes of relaxation after procedure
Basti kadha	Per-rectal drug administration should be in body for ≥ 15 minutes for maximum absorption	Mixture of 40% *Guduchi*(Tinospora cordifolia), 20% *Daruharidra* (Berberis aristata) and 40% *Yashtimadhu* (Glycyrrhiza glabra)	10 minutes

Table.2 Baseline characteristics of the study participants

Variable	N=89
Age (Years)	56.19 ± 10.98
Gender n (%)	
Male	52 (58.4)
Female	37 (41.6)
Co morbidities n (%)	
Hypertension	39 (43.82)
Obesity	15 (16.85)
Dyslipidemia	10 (11.24)
Ischemic heart disease	8 (8.99)
Coronary artery disease	5 (5.62)
Chronic heart failure	3 (3.37)
Hypothyroidism	3 (3.37)
Chronic kidney disease	1 (1.12)
H/O Coronary angioplasty	1 (1.12)

Age is expressed in mean ± SD and N (%)

Table.3 Comparison of various body parameters at the Baseline and after 90 days of the treatment

Variable	Baseline	After 90 days	t-statistic	p-value
HbA1c	9.02 ± 1.79	6.86 ± 1.24	12.78	<0.001***
BMI (Kg/m^2)	27.24 ± 1.33	25.39 ± 1.53	15.242	<0.001***
Abdominal girth	97.12 ± 7.03	91.64 ± 6.26	10.68	<0.001***
SBP (mmHg)	131.60 ± 16.10	122.83 ± 13.56	5.65	<0.001***
DBP (mmHg)	81.75 ± 9.43	77.02 ± 6.81	5.23	<0.001***

****Highly significant; BMI: Body Mass Index, HbA1c: Haemoglobin A1c, SBP: Systolic blood pressure, DBP: Diastolic blood pressure*

Table.4 Correlation between Abdominal Girth, HbA1c & Abdominal Girth, BMI

Correlation between	Baseline		After 90 days	
	r	p-value	r	p-value
Abdominal girth and HbA1c	0.018	0.87	0.183	0.084
Abdomen girth and BMI	0.28	0.007	0.48	<0.001
HbA1c and BMI	-0.008	0.94	0.12	0.26

Table.5 Consumption of medicines at baseline and after 90 days

Medicine	Day 1	After 90 days
Sulfonylurea	39 (43.82)	22 (24.72)
Biguanide	54 (60.67)	33 (37.08)
Alpha-glucosidase inhibitor	13 (14.61)	7 (7.87)
DPP -4 inhibitor	17 (19.1)	2 (2.25)
Thiazolidinedione	2 (2.25)	9 (10.11)
Insulin	7 (7.87)	1 (1.12)
Beta blocker	11 (12.36)	6 (6.74)
ACE inhibitor	2 (2.25)	0 (0)
ARB	20 (22.47)	14 (15.73)
CCB	14 (15.73)	7 (7.87)
Diuretic	9 (10.11)	4 (4.49)
Statin	26 (29.21)	10 (11.24)
NSAID	14 (15.73)	8 (8.99)
No medicine	13 (14.61)	40 (44.94)

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Fig.3 Comparison of abdominal girth of the patients at baseline and after

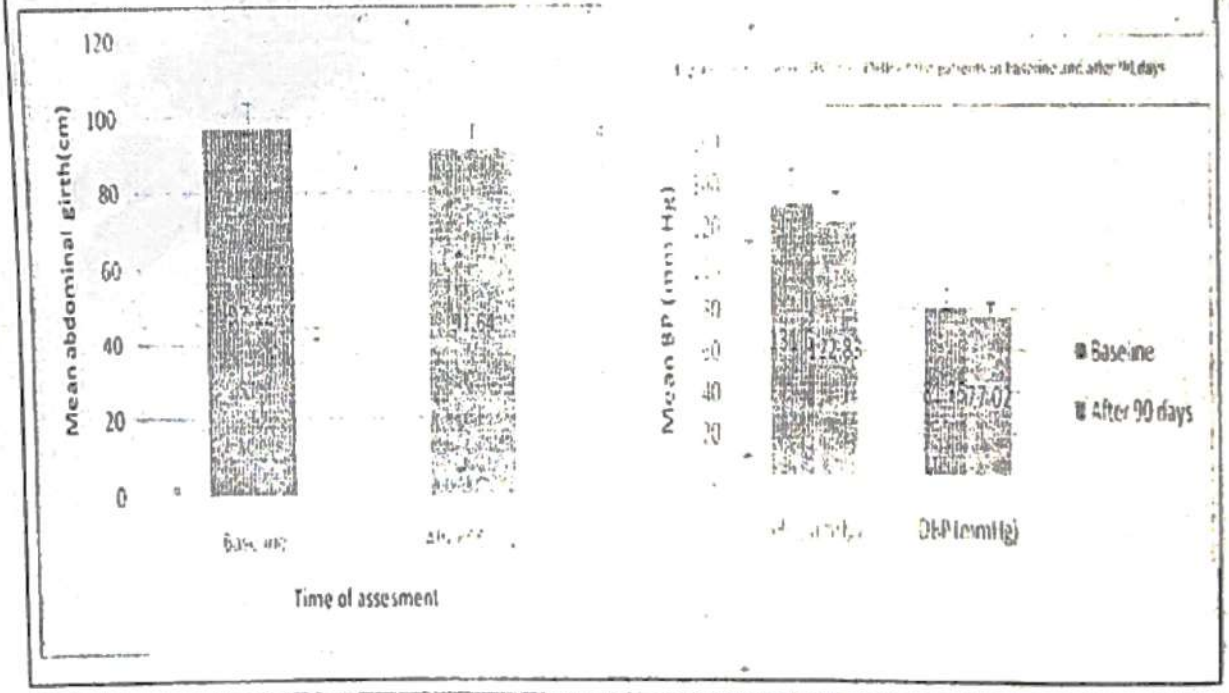

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Fig.5 Correlation between Abdominal Girth, HbA1c & Abdominal Girth, BMI

Fig 5.1: Abdominal girth & HbA1c at1stday

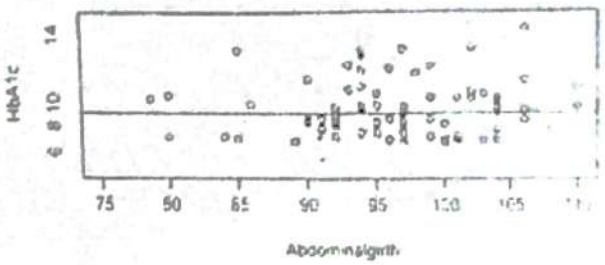


Fig 5.2. Abdominal girth & HbA1c at 90thday

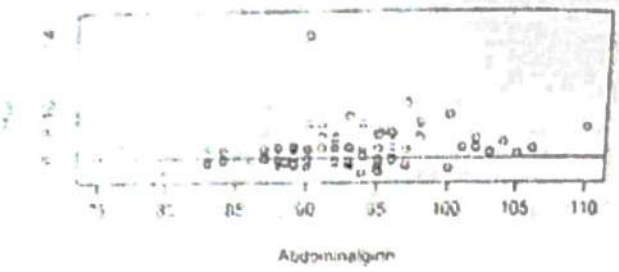


Fig 5.3: Abdominal girth &BMI at1stday

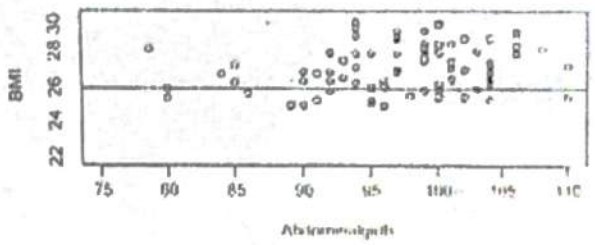


Fig 5.4. Abdominal girth &BMI at 90thday

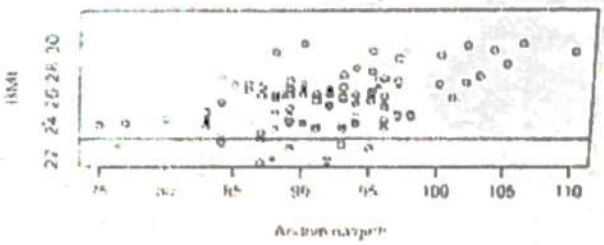


Fig 5.5: HbA1c &BMI at1stday

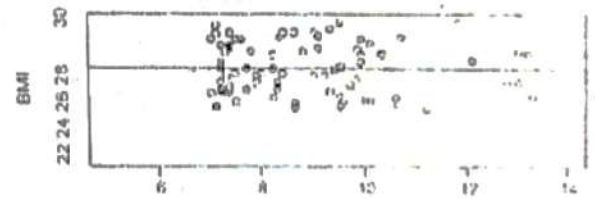


Fig 5.6 HbA1c &BMI at 90th day

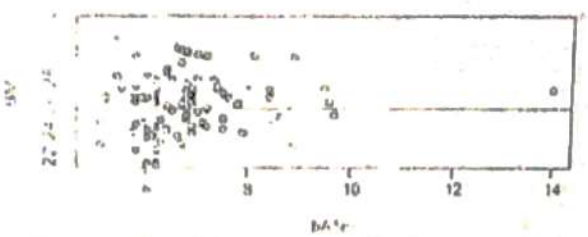
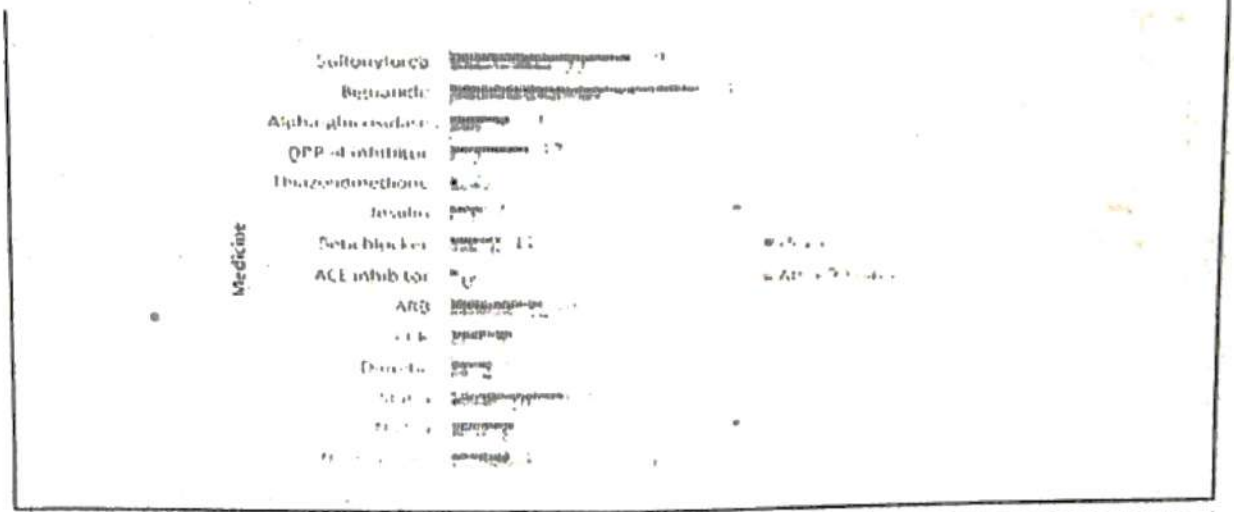


Fig.6 Consumption of medicines at baseline and after 90 days



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*Snehana*is provided using *Neem* (*Azadiractaindica*) oil all over the body. Oleation is an anxiolytic procedure which decreases the sympathetic stress. The reduced sympathetic action decreases the hepatic glucose production, which can be helpful to reduce blood sugar levels. *Azadiractaindica*has antibacterial and antifungal action that can also help to reduce skin infections in DM patients (Subapriya and Nagini, 2005) *Swedana*is a process wherein diabetic patients get sleep inside a wooden box full of steam with head and neck outside the box, temperature being maintained around 40-45-degree Celsius. After 15-20 min patient is asked to come outside the box. It is hypothesized that hot fomentation, which is a relaxing process, induces sweating and decreases the excess of sodium and water which comprehensively helps to improve vascular health of DM patient to keep them away from probable vascular complications. *Basti* involves per rectal administration of ayurvedic herbal extracts like *Gudmar*(*Gymnemasylvestre*), *Daruharidra*(*Berberis aristate*) and *Yashtimadhu*(*Glycyrrhiza glabra*). *Gymnemasylvestre*has been found to stimulate insulin release, which may be responsible for its possible anti-hyperglycaemic action. (Persaud, 1999) The insulin release may be due to the possible regeneration of islet of Langerhans, as mentioned in a study conducted on streptozotocin -diabetic rats. (Shanmugasundaram*et al.*, 1990) An animal study assessed the anti-hyperglycaemic action of *Berberis aristate* and found strong potential in regulating homeostasis. (Singh and Kakkar, 2009) A clinical study conducted in type 2 DM patients found that *Berberis aristate* can reduce HbA1c efficiently. (Di Pierro*et al.*, 2013) In a pre-clinical study, *Glycyrrhiza glabra* has been found to prevent the deleterious effects of DM on learning and memory. (Hasanein, 2011) It is, however, important to note that low carbohydrate diet of 800 calories/day was advised to these patients throughout the 90 days period that could have add on benefit to this intervention.

Diabetes is known to be associated with poor dietary choices. Dietary choices is a key driver for insulin resistance, especially in an aging and sedentary population. Increased consumption of calorie-dense foods like fast food, meats and other animal fats, highly refined grains, and sugar-sweetened beverages, are thought to play a critical role in the rising rates of type 2 diabetes worldwide Dietary changes like intake of low calories & high consumption of complex carbohydrates like high intake of fruits and vegetables, legumes, nuts, good quality fat can help in reducing insulin resistance. As per one of the studies, beta cell failure & insulin resistance can be alleviated by acute negativeenergy balance. Fasting blood glucose and hepatic insulin sensitivity reduced to normal & intrahepatic lipid decreased by 30% over 8 weeks and beta cell function elevated towards normality. (Lim, 2011; Yancy, 2005; Sami, 2017; McMacken and Shah, 2017)

For weight loss one should reduce to around

1000kcal/day which will help reduce 1 kg of body weightper week & 4kg per month Low calorie and low carbohydrate diet helps in utilization of intra organ fat and reduces insulin resistance which will help in the reversal of diabetes. Diet plan recommended to the patients was based on this principle of low-calorie and low-carbohydrate diet, which is to be followed for 12 weeks. It is based on pulse protein, complex carbohydrates, consumption of fruits and vegetables as well as good quality fats. As the diet plan is low in calories, it can lead to normalise insulin secretion and controldiabetes.

This study had a few limitations. It was a single-arm, retrospective study due to which the results were not compared with the standard care. However, this study was a proof-of-concept research, and future cohort studies with larger sample size and longer duration follow-up may be conducted, to generate a stronger evidence.

Treatment with CDC showed a significant decrease in the HbA1c levels of diabetic patients. CDC also showed significant reduction in the metabolic parameters of weight, BMI and abdominal girth of the diabetic patients. Moreover, CDC also decreased the dependency of the diabetic patients on the standard allopathicmedications.

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Efficacy of a polyherbal oral formulation in the management of essential hypertension: an open label, pilot clinical study

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ABSTRACT

Background: Effective control of blood pressure in patients with hypertension decreases cardiovascular mortality. However, many hypertensives are unresponsive to standard antihypertensive treatment. Research has found anti- hypertensive potential in the Ayurvedic drugs Brahmi (Bacopa monnieri) and Shunthi (Zingiberofficinale). Hence, a pilot study was conducted to evaluate the efficacy and safety of Capsule Artyl (the oral formulation of Brahmi and Shunthi) as a treatment option in hypertensive subjects.

Methods:Therewere30hypertensivesubjects attendingout-patientdepartments ofclinicsinMaharashtra,Indiawereenrolledinthisf our-week,openlabel,single arm study. All subjects received capsule Artyl(500mg) twice a day orally daily. The mean systolic (SBP) and diastolic blood pressure (DBP) on days 1 and 28 of the study were compared along with the mean arterial pressure(MAP).

Results: The mean SBP was significantly lesser on day 28 (141.86±12.54mm Hg) as compared to the mean SBP recorded on day 1 (155.48±19.37mm Hg) (p<0.001). The mean DBP on day 28 (89.66±6.8mm Hg) was lesser than that on day 1 (90.34±7.44mm Hg) but this difference was not statistically significant (p>0.05). There was a significant decrease in the mean value of MAP on day 28 (107.06±7.03mm Hg) as compared to that on day 1 (112.06±10.75mm Hg) (p<0.01).

Conclusions: Capsule Artyl significantly decreased the BP in hypertensive patients, without any adverse effects. Controlled trials are needed to confirm the positive outcome of this promising herbal formulation in hypertensive patients

Keywords: Capsule artyl, Essential hypertension, Systolic blood pressure

INTRODUCTION

Hypertension has become a crucial health issue to tackle worldwide not only due to its increasing prevalence but also because of the severe complications associated with it. About 10-15% of the rural and 25% of the urban population are estimated to be affected by hypertension in India. Also, Government of India has estimated that by 2020, 159.46/1000 Indians will be suffering from hypertension.1,2 Moreover, multiple complications associated with hypertension is a cause of high mortality due to the disease. According to the World Health Organization (WHO) data released in 2014, 26% of the

deaths in India are due to cardiovascular disease. Another striking data is that 29% of strokes, 21% of acute myocardial infarction and 16% of ischemic heart disease in India are all attributed to hypertension.3

Thecurrentmanagementofhypertensioninvolv eslifestyle modifications along with pharmacotherapy. The pharmacological agents used for the treatment include angiotensin converting enzyme (ACE) inhibitors, angiotensin receptor blockers (ARBs), calcium channel blockers (CCBs), diuretics and alpha blockers. However, these agents are not enough to control the blood pressure of patients. It has been

estimated that in more than two- third hypertensive patients on treatment, theblood pressure cannot be controlled with a single pharmacological agent and they require multipledrugs.4 A recent Indian study has revealed that the control rates of blood pressureinhypertensivecasesareaslowas1/10thi n rural and 1/5thin the urban population.5 Other pitfalls of the pharmacological agents for hypertension include the plethora of adverse effects as well as the high costs associated with their use. Hence, there is a strong need to search safe and cost-effective options for the management of hypertension inIndia.

Ayurveda, the Indian traditional discipline of medicine, has been usedby various physicianstotreatmultipletypes of disorders. However, many of the herbal extracts have not been investigated thoroughly for their possible beneficial effects in the treatment of hypertension. Two of such herbal drugs are Brahmi (Bacopa monnieri) and Shunthi (Zingiberofficinale). In Ayurveda, Brahmi is considered to be a powerful Medhya (brain tonic) and has been widely studied for its nootropic effect. However, it has also shown promiseasananti -stressaswell asanantioxidative agent.6 There have been very few studies which have tried to evaluate the effect of Brahmi as an anti- hypertensive agent.7,8 Shunthi, the processed dry ginger is a popular herb used extensively in the Indiansubcontinent as a food additive. The beneficial effect of Shunthi in cardiovascular disease has been known for long.9 According to a systematic review published by the British Medical Journal, manyanimalstudieshaveestablishedthe beneficial effect of Shunthi as a dietary supplement to conventional anti-hypertensive drugs. However, the same review has stated the need for more clinical studies to assess the possible effect of Shunthi in hypertensive patients.10

Capsule Artylis a polyherbal Ayurvedic oral formulation which is made from the aqueous extracts of Brahmi (Bacoside 30%) and Shunthi (Gingerol 2.5%). Considering the beneficial anti-hypertensive effect of both these extracts individually, this combination looks like a promising agent that can help physicians, as well as the patients, tackle the grave problem of uncontrolled hypertension. Hence, we planned to conduct an open label pilot study to assess the efficacy and the safety of this promising herbal combination in patients suffering from essential hypertension at various health care centers in Maharashtra, India.

METHODS

This study was a four-week, open label, single arm, multicentric, pilot study which was conducted to evaluate the effect of capsule Artyl on blood pressure in hypertensive patients.

There were 30 patients belonging to the age group of 30 years to 70 years having pre-diagnosed essential hypertension with systolic blood pressure (SBP) between 140-170mm Hg were included in this study. These subjects were attending the out-patient departments

(OPDs) at different Madhavbaug clinics located invarious cities of Maharashtra, India. The subjects enrolled in the study had to be willing to follow the protocol strictly over the four weeks of study period. Patients who were suffering from cardiovascular co-morbidities (left ventricular hypertrophy, heart block, congestive heart failure or coronary artery disease) were excluded from the study. Patients having deranged liver function tests or renal function tests, pregnant women or women planning pregnancy in the next 6 months were also excluded from the study. If the subjects failed to adhere to the protocolor decided to drop out of the study themselves or developed some complication due to increase in SBP and diastolic blood pressure (DBP) which would have required urgent treatment, then they were to be withdrawn from thestudy.

The study was initiated in November 2017 and completed in February 2018. The patients were prescribed capsule Artyl 500mg, to be taken twice daily for a period of 28 days, along with the conventional treatment, if it was ongoing for the

patient.All the patients were motivated to modifytheirlifestyleanddietaryhabits.Theassessmentof SBP and DBP was done with the help of a sphygmomanometer after enrolment of the subject in the study,whichwasconsideredthebaselineorday1reading. The follow up reading of SBP and DBP was taken at day 7,day14,day21 and day28.Theweight,height,BMIand the concomitant medication data was noted down on day1 and again on day 28. The mean arterial pressure (MAP) was also calculatedforall the patientson day1 andday28 using the formula: 2/3rdDBP + 1/3rdSBP.

Data were analyzed using MS excel and GraphpadInstatsoftwares. The data were represented as mean±SD. The variablesonday 1andday28werecomparedtoeachother using paired student's t test. P value of less than 0.05 was considered significant for all thevariables.

Table 1: Constituents of capsule Artyl.

Composition of Cap Artyl	Percentage (%)
Brahmi (*Bacopa monnieri*)	62.5
Shunthi (*Zingiberofficinale*)	34
Excipient	3.5

RESULTS

A total of 90 hypertensive patients were screened for participation in the study. Out of these 90 patients,30were included in the study based on the selection criteria. 29 of the30enrolledpatientscompletedthefullstudyperiodand the data collected from these 29 patients were analyzed at the end of the study (Figure 1). The demographic details of the patients have been mentioned in Table2.

Many of the patients (n=11) were found to have hypertension for the first time on their visit to the Madhavbaug Clinic OPDs. These 11 patients were started on Capsule Artyl with the advice of lifestyle and dietary modifications. The remaining 18 patients were on concomitant allopathic medications, the details of which have been mentioned in Figure 2

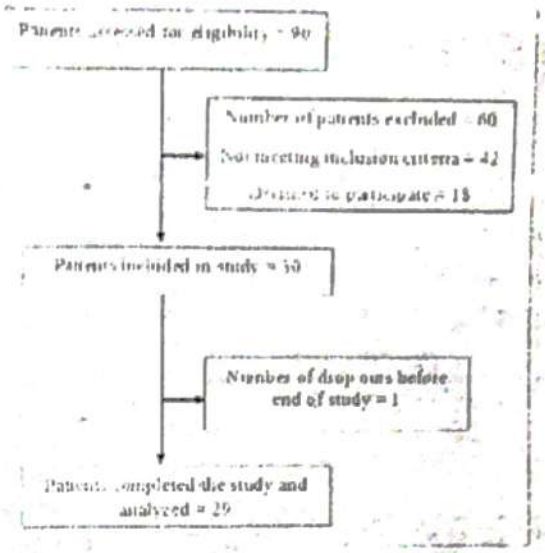


Figure 1: Patient enrolment flow chart.

Table 2: Demographic details of patients enrolled in the study (n= 29).

Sr. No.	Demographic details of the study participants
	Mean age of patients = 51.68±14.02 years
	Mean weight of patients (Day 1) = 70.29±10.65 kilograms
	Mean weight of patients (Day 28) = 70.12±10.80 kilograms
	Mean BMI of patients (Day 1) = 27.08±3.21kg/m^2
	Mean BMI of patients (Day 28) = 26.53±3.02kg/m^2

Table 3: Effect of artyl treatment on improvement of Systolic Blood Pressure (SBP) from baseline to day 28.

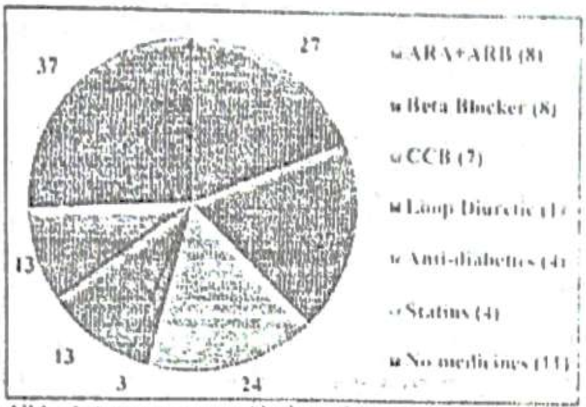
SBP	No. of Patients	Baseline	Day 28	Changes	% Changes
1 All					
Mean	29	155.48	141.86	13.62	8.76
Standard deviation		10.61	12.54		
P value		P < 0.001			

Table 4: Effect of artyl treatment on improvement of Diastolic Blood Pressure (DBP) from baseline to day 28.

DBP	No. of Patients	Baseline	Day 28	Changes	% Changes
1 All					
Mean	29	90.34	89.66	0.69	0.76
Standard deviation		6.68	6.80		
P value		P = 0.05			

Table 5: Effect of Artyl treatment on improvement of Mean Arterial Pressure (MAP) from baseline to day 28.

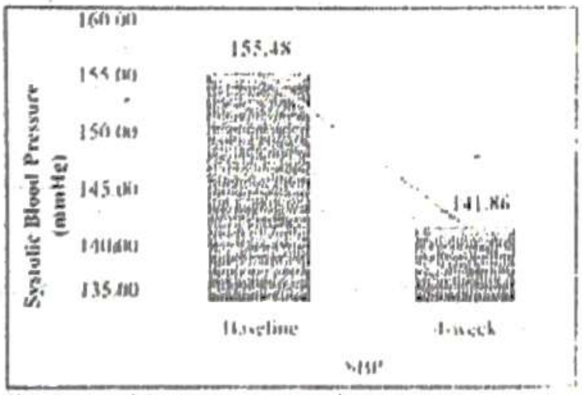
DBP	No of patients	Baseline	Day 28	Changes	% Change
All					
Mean	29	112.06	107.06	5.00	4.46
Standard deviation		6.29	7.03		
P value	P<0.01				



ARA= Antagonist receptor blocker, ARB= Angiotensin Receptor Blockers, CCB= Calcium ChannelBlockers

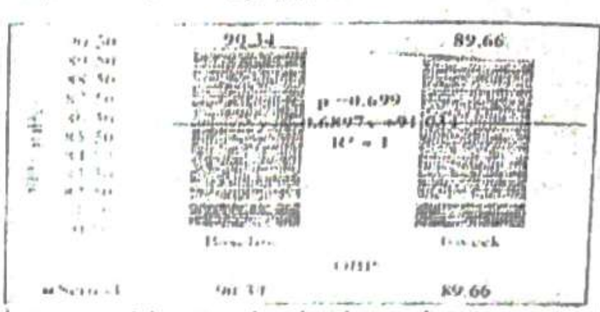
Figure 2: Percentage of subjects using allopathy medicines (n=29).

The mean SBP on day 28 was compared with that at baseline using Paired t-test; P<0.05 considered significant (Table 3). The efficacy parameters were analyzed at baseline (day 1) and on the last day of the study (day 28). Itwasfoundthatthemean SBPwassignificantlylesseron day 28 (141.86±12.54mm Hg) as compared to the mean baseline SBP of the patients recorded on day 1 (155.48±19.37mm Hg) (p<0.001). The decrease in the mean SBP was by a margin of 8.76% (Figure3).



Comparison of the mean values done by paired t-test.
* p<0.05 considered a statistically significant difference

[illegible] DBP on day 28 [illegible] 6.8mm Hg) was lesser than that [illegible] Hg) but this difference [illegible] significant (p [illegible] 0.05). The decrease in [illegible]



Comparison of the [illegible] done by paired t-test
[illegible] different from each other (p [illegible] 0.05)

Figure 4: Comparison of mean Diastolic Blood Pressure at baseline and at 4 weeks (n=29).

Comparison of the mean values done by paired t-test.
* p<0.05 considered a statistically significant difference

Figure 5: Comparison of mean values of mean arterial pressure at baseline and at 4 weeks (n=29).

There was asignificant decreasein the meanvalueofMAP on day 28 (107.06±7.03mm Hg) as compared to that on day 1 (112.06±10.75mm Hg) (p<0.01). The difference in the mean values of MAP was 4.46% (Figure 5). None of the participants in the study developed anykindofadverse event over the studyperiod.

DISCUSSION

Hypertension is one of the most common and dangerous non-communicablediseas eaffecting the world population. The complications associated with the disease is a grave concern, especially because of the high rates of uncontrolled BP in the patients with hypertension, despite being on the standard pharmacological treatment. An Indian study published in 2014 concluded that the control rates of blood pressure in hypertensive cases on medication are just about 10% in rural and 20% inthe urban population.5 Current drugs used for

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hypertension are not only associated with adverse effects but are also not cost-effective.11 Hence, it is important to look to alternative medicine for more efficacious, safe and cost-effective options to treat hypertension. This search took us to Ayurveda, the Indian discipline of traditional medicine. Two herbal drugs, namely Brahmi (Bacopa monnieri) and Shunthi (Zingiberofficinale) have been studied by researchers for their possible anti-hypertensive effect individually. However, none of them has studied a combination of these herbal medicines for the treatment of hypertension. Capsule Artylis a herbal drug made by combining the extracts of Brahmi and Shunthi. Considering the surrounding evidence and the need for new medicines to control hypertension, we conducted this study.

On analyzing the collected data from the 29 participating hypertensive patients, we found that there was a statistically significant decrease in the mean SBP and the mean values of MAP on day 28 as compared to the baseline reading. The mean DBP was also found to be lower on day 28 as compared to the baseline reading, however this difference was not statistically significant. None of the patients on capsule'Artyl showed any adverse effect in the study, and thus the formulation can be considered safe. These results were in sync with many of the studies conducted using Brahmi and Shunthi individually.

In a preclinical study conducted in Thailand, it was found that Brahmi reduces the blood pressure significantly in Wistar rats.7 In a clinical study conducted in India,Brahmi was found to decrease SBP, DBP and MAPsignificantly at 4 weeks of treatment, similar to the findings in this study.8

Shunthi, the processed dry ginger, has shown promising results individually in various studies as an anti- hypertensive agent. In a study conducted in China, daily consumption of ginger was associated with decreased risk of hypertension in adults (OR = 0.92 CI 0.87-0.99).12 A clinical study conducted in hypertensive patients of Egypt showedastatisticallysignificantdecreaseinSBPandDBP at the end of 4 weeks of taking ginger with the prescribed medication.13 A systematic review on ginger published in the British Medical Journal concluded that animal studies have found ginger to have the potential to offer natural anti-hypertensive effect when taken as a supplement to conventional anti-hypertensivedrugs 10

Preclinical studies have assessed the possible mechanism of actions behind the antihypertensive effects of Brahmi and Shunthi. The study conducted by Kamkaew et al. found that the fall in blood pressure caused by Brahmi is because of its vasodilatory effects on the resistance arteries. The researchers also found that this vasodilation is through the nitric oxide pathway. At high concentrations, Brahmi was found to decrease the contractions generated by the voltage gated calcium

channels and reduce the action of calcium release fromthe sarcoplasmic reticulum.7 Brahmi has also shown anti- stress as well as anti-oxidant property, which may also play a role in its anti-hypertensive action. A pre-clinical study in Nigeria found that Shunthi (ginger) showed ACE inhibitory activity in vivo which could be the reason behind its BP lowering action.14 A study conducted by Ghayur et al found that ginger exhibited a vasodilator action through the blockage of the voltage gated calcium channels, which may be another possible mechanism behind its anti-hypertensiveaction.9

Our study had a few limitations. It was a one arm pilot study which was done mainly as a proof of concept research with low sample size and without a control arm. Sphygmomanometer was used to assess the SBP and the DBP, which is a subjective tool to measure BP in comparison to ambulatory BP monitoring. The study duration was just 28 days, due to which long term efficacy and safety of capsule Artylwas not assessed.

CONCLUSION

Our preliminary studyhas found that capsule Artyl, which is a herbal drug produced by

combining Brahmi and Shunthi, is successful in significantly decreasing the BP in hypertensive patients, without any adverse effects Considering that this wasapilotone-armstudy. controlled trials with larger sample size are needed to confirm the positive outcome of this promising herbal drug in hypertensive patients

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Conflict of interest: None declared

Ethical approval: The study was approved by the Institutional Ethics Committee

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