Quality of Life and Clinical Efficacy of a Locally Used Polyherbal Formulation Among Type II Diabetes Patients

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Introduction

Diabetes mellitus is a group of metabolic disorders characterized by hyperglycemia resulting from defects in Insulin secretion, Insulin action or both.

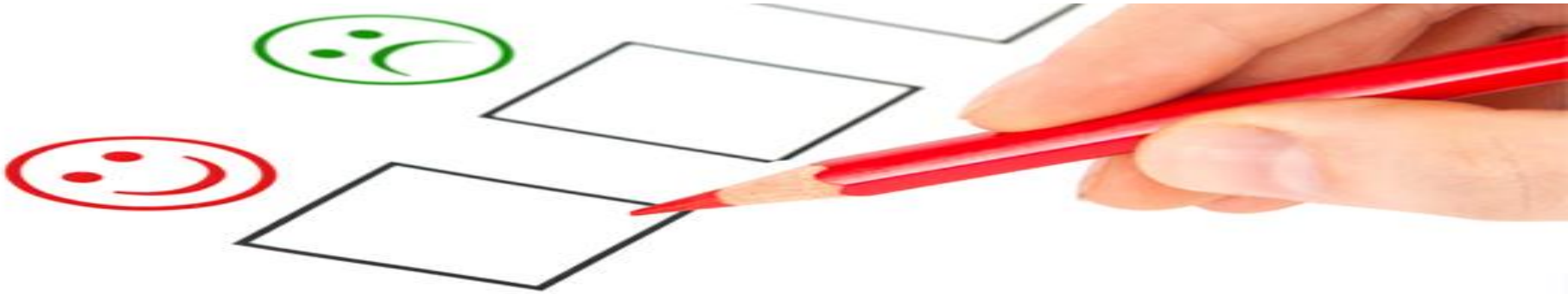
Risk factors among diabetes patients

1. Obesity
2. Sedentary Lifestyle
3. Unhealthy Eating Habits
4. Family History and Genetics
5. Increased Age /Stress
6. High Blood Pressure and High Cholesterol

Introduction *(Contd)*

Importance of patient satisfaction in antidiabetic therapy:

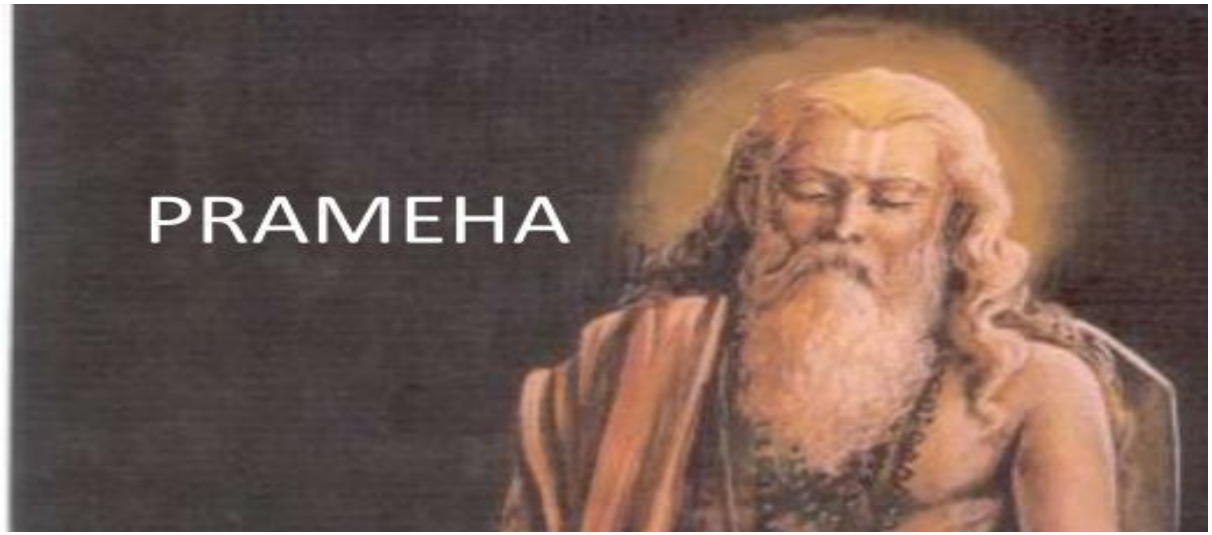
1. Plays an important role in diabetes management for optimum glycemic control
2. Only few instruments are available
3. Important step toward building and maintaining a therapeutic alliance



Introduction *(Contd)*

Diabetes Mellitus and Ayurveda:

- Called as 'Prameha‘ in terms of ayurveda
- Ayurveda, advocates the holistic approach to the disease and advises the treatment in totality.



Introduction *(Contd)*

INSOL-N

- Ayurvedic proprietary medicine
- New dimension in treatment of DM
- Is a combination of more than 16 ayurvedic antidiabetic herbs.

Literature Review

Insol - N is a Ayurvedic formulation, which is found to be a useful oral health supplement in diabetics.

Indications

- In type 2 diabetes Diabetes Mellitus
- As an adjuvant in type 1 diabetes along with Insulin therapy.

Literature Review *(Contd)*

- **Dosage:** In type 2 diabetes: Initially 2 tablets thrice daily followed by a maintenance of 2 tablet twice daily.

Objectives

- To find out the clinical efficacy of Insol- N in type 2 diabetic patients
- To measure improvement in QoL among type II diabetes patients taking Insol-N
- To measure patient satisfaction with respect to this medication among type II diabetes patients taking Insol-N

Research Methodology

Study design:

Prospective observational study design

Sources of data:

- **Primary Data**

  Patient Case Records

  Interviewing the patients

- **Secondary Data**

  Internet websites, Ayurvedic Text books, Journals.

Research Methodology *(Contd)*

Sampling plan:

- **Sampling unit:** Type II diabetic patients prescribed with Insol-N

- **Sample Size:**

  Proposed sample size: 50 patients with Diabetes Mellitus on INSOL-N

  Total Patients participated: 53

  No. of patients completed the study: 51 (1 patient withdrawn, 1 patient dropped out)

- **Sampling method:** Non probability sampling with convenience method.

Research Methodology *(Contd)*

Inclusion Criteria

- ✓ All type II diabetes mellitus patients
- ✓ Age 18 – 75 years
- ✓ Patients with Diabetes Mellitus taking only INSOL-N tablets
- ✓ Patients who agreed to sign ICF
- ✓ Patients in whom the treatment pattern will not change till 3 months

Research Methodology *(Contd)*

Exclusion Criteria

- ✓ Type I diabetes patients.
- ✓ Pregnant ladies.
- ✓ Lactating women.
- ✓ Chronically ill patients.
- ✓ Patient who are on life style modification or on diet therapy (pre diabetic patient).
- ✓ Patient who refused to be part of the study.

Research Methodology *(Contd)*

Study site

This study was conducted in group of patients receiving INSOL-N tablets for the treatment of type II diabetes mellitus in and around Udupi and Manipal region.

Study Duration

Total duration of the study was 6 months.

Research Methodology *(Contd)*

Ethical Approval

Ethical Clearance was obtained from the Muniyal Institute of Ayurvedic and Research center, Manipal. Protocol number is MAHR/12/201

Pilot study

A small pilot study was conducted before starting the main study by interacting with the practitioners and changing the designs of the questionnaire as well as data collection form as per our requirements. Sample size of 5 patients was used for this study

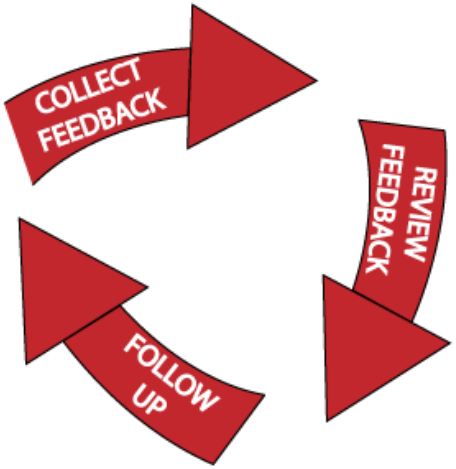
Research Methodology *(Contd)*

Research Instruments:

- Patient Data Collection Form
- DMSAT Questionnaire
- QOL Questionnaire
- Kuppuswamy socio-economic scale

Follow up

Feedback



Results and Discussion

Demographics:

Total no. of patients participated: 53

Total no. of patients completed the study: 51

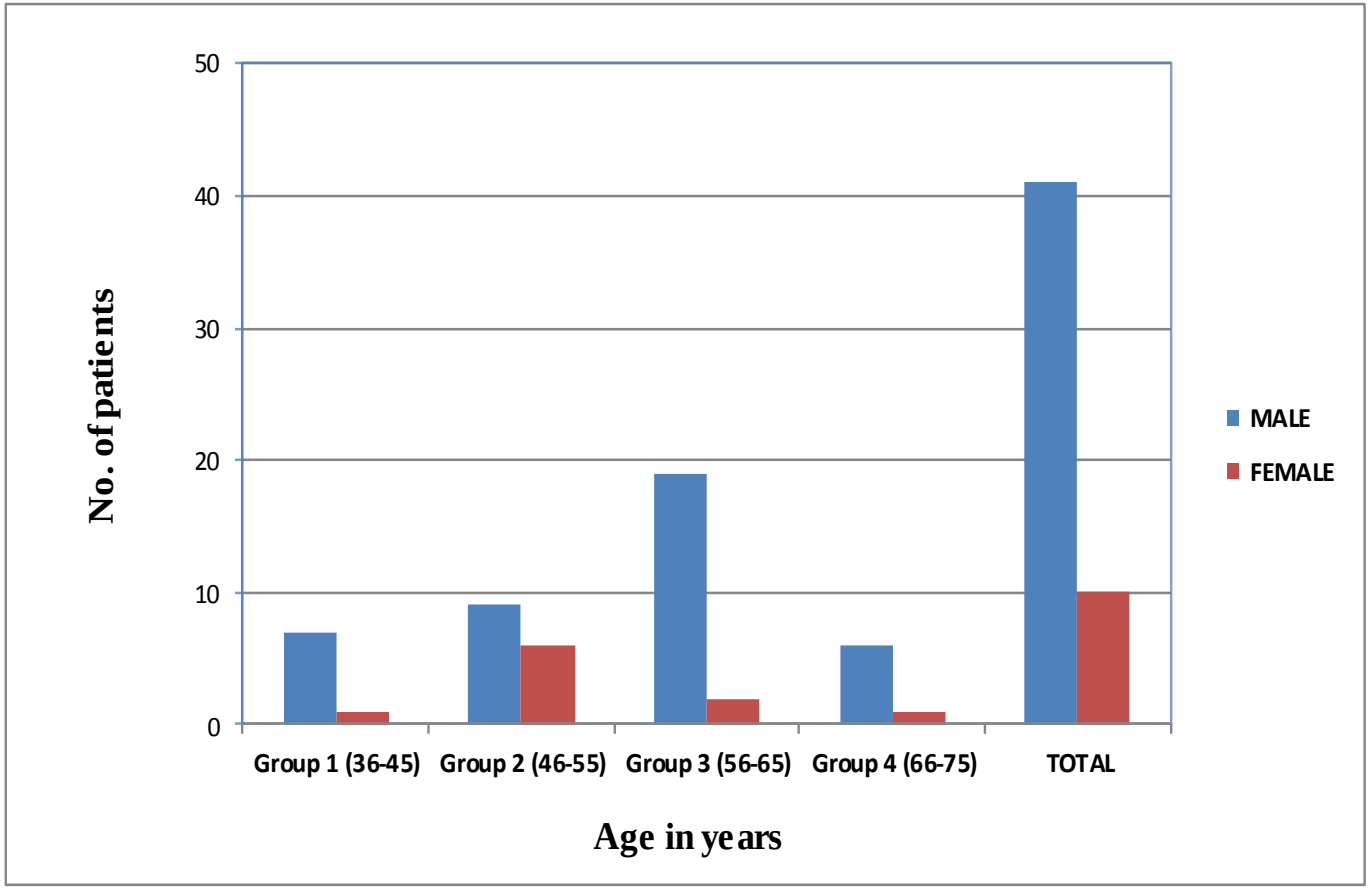
Total no. of male patients: 41

Total no. of female patients: 10

No. of patients in each group	MALE	FEMALE	Total
Group 1 (36-45)	7	1	8
Group 2 (46-55)	9	6	15
Group 3 (56-65)	19	2	21
Group 4 (66-75)	6	1	7
TOTAL	41	10	51

Demographic data for FBS estimation

Results and Discussion *(Contd)*

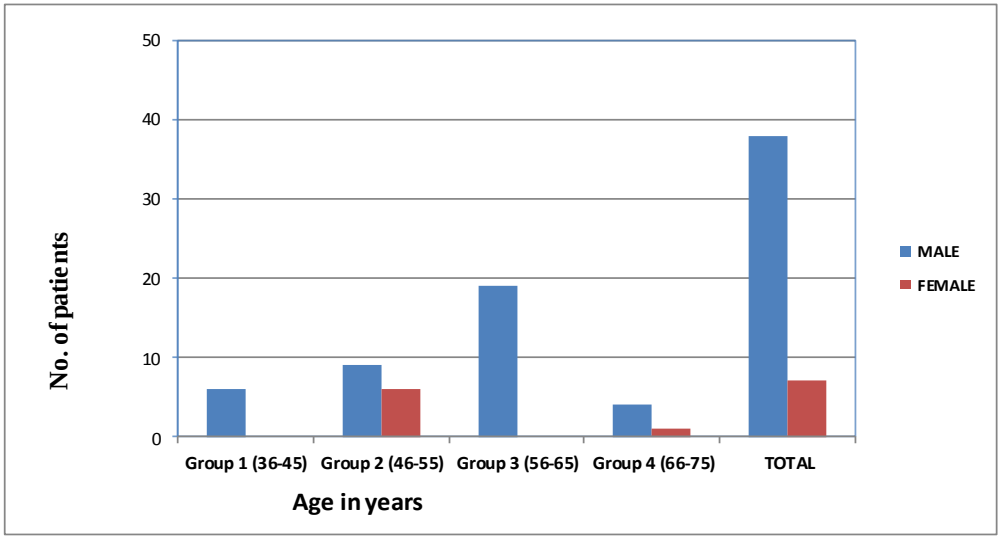


Demographic data for FBS estimation

Results and Discussion *(Contd)*

Demographic data for HbA1c estimation

No. of patients in each group	MALE	FEMALE	Total
Group 1 (36-45)	6	0	6
Group 2 (46-55)	9	6	15
Group 3 (56-65)	19	0	19
Group 4 (66-75)	4	1	5
TOTAL	38	7	45

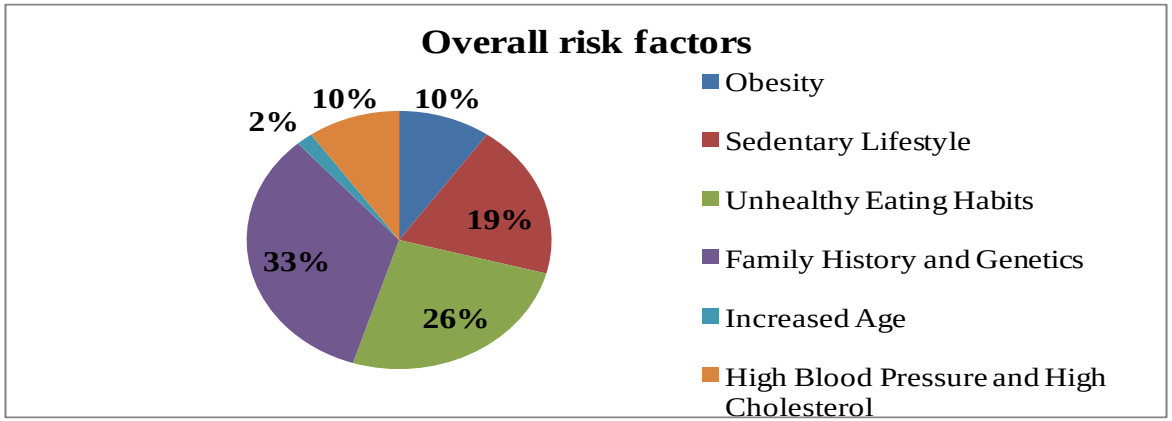


Results and Discussion *(Contd)*

- **Risk factor analysis: Individual risk factors**

Individual risk factors

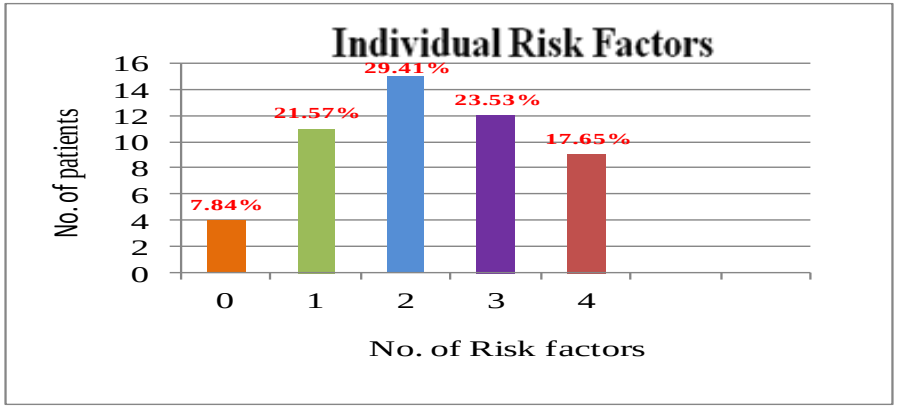
Risk factors	Total no. of patients
Obesity	11
Sedentary Lifestyle	22
Unhealthy Eating Habits	29
Family History and Genetics	38
Increased Age/Stress	2
High Blood Pressure and High Cholesterol	11



Results and Discussion *(Contd)*

- **Multiple risk factors:**

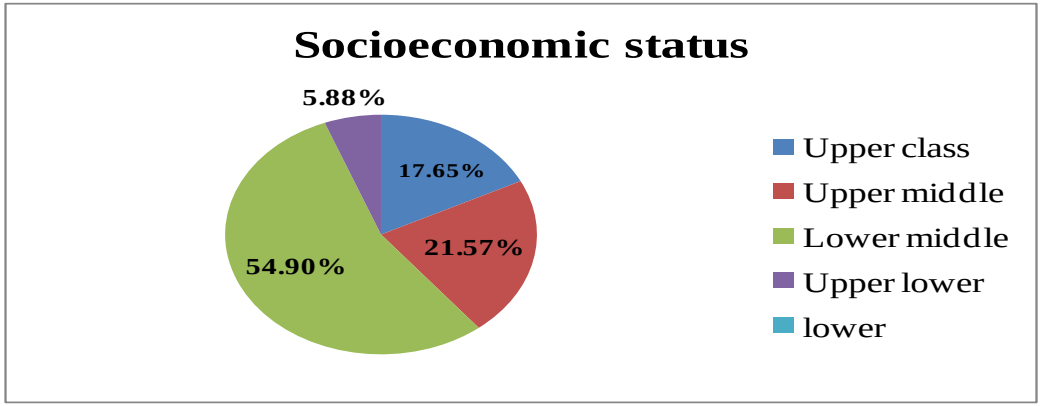
No. Risk factors	No. of patients
0	4
1	11
2	15
3	12
4	9
5	0
6	0



Results and Discussion *(Contd)*

- **Socioeconomic status**

Serial no.	Score Category		No. of patients
1	26 to 29	Upper class	9
2	16 to 25	Upper middle	11
3	11 to 15	Lower middle	28
4	5 to 10	Upper lower	3
5	less than 5	lower	0
Mean score ± SD	16.53±5.49	Upper middle class	



Results and Discussion *(Contd)*

Clinical Efficacy

Efficacy was calculated by measuring the fasting blood glucose level and HbA1c at four intervals that is on Day 1, Day 15, Day 30 and Day 90.

Results were tabulated in following manner:

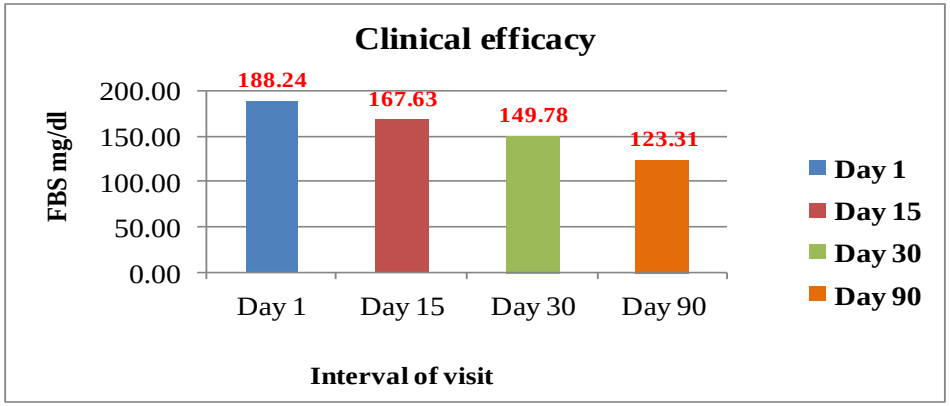
1. Overall patient efficacy data
2. Age wise clinical efficacy data
3. Gender wise clinical efficacy data
4. Risk factor wise clinical efficacy data

Results and Discussion *(Contd)*

1. Overall Patient clinical data

- FBS Data:

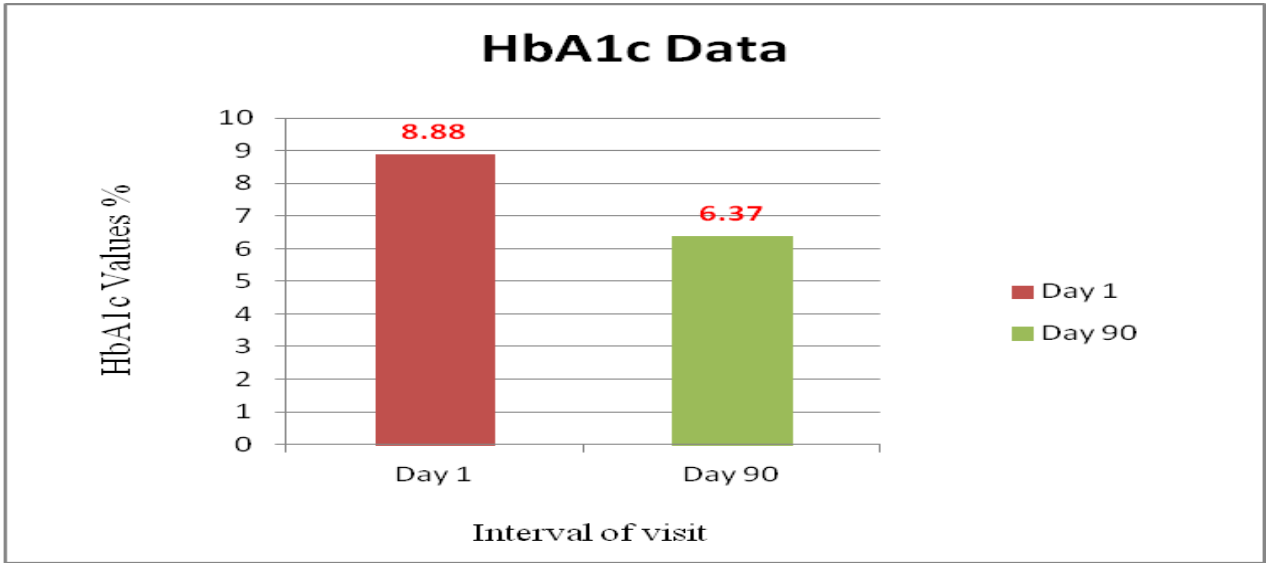
	Mean ± SD (mg/dl)	% Reduction
Day 1	188.24± 41.39	34.49%
Day 15	167.63 ± 35.24	
Day 30	149.78± 33.58	
Day 90	123.31 ± 25.97	



Results and Discussion *(Contd)*

- HbA1c data:

	Mean±SD (%)	% Reduction
Day 1	8.88± 1.67	28.27%
Day 90	6.37 ± 0.98	



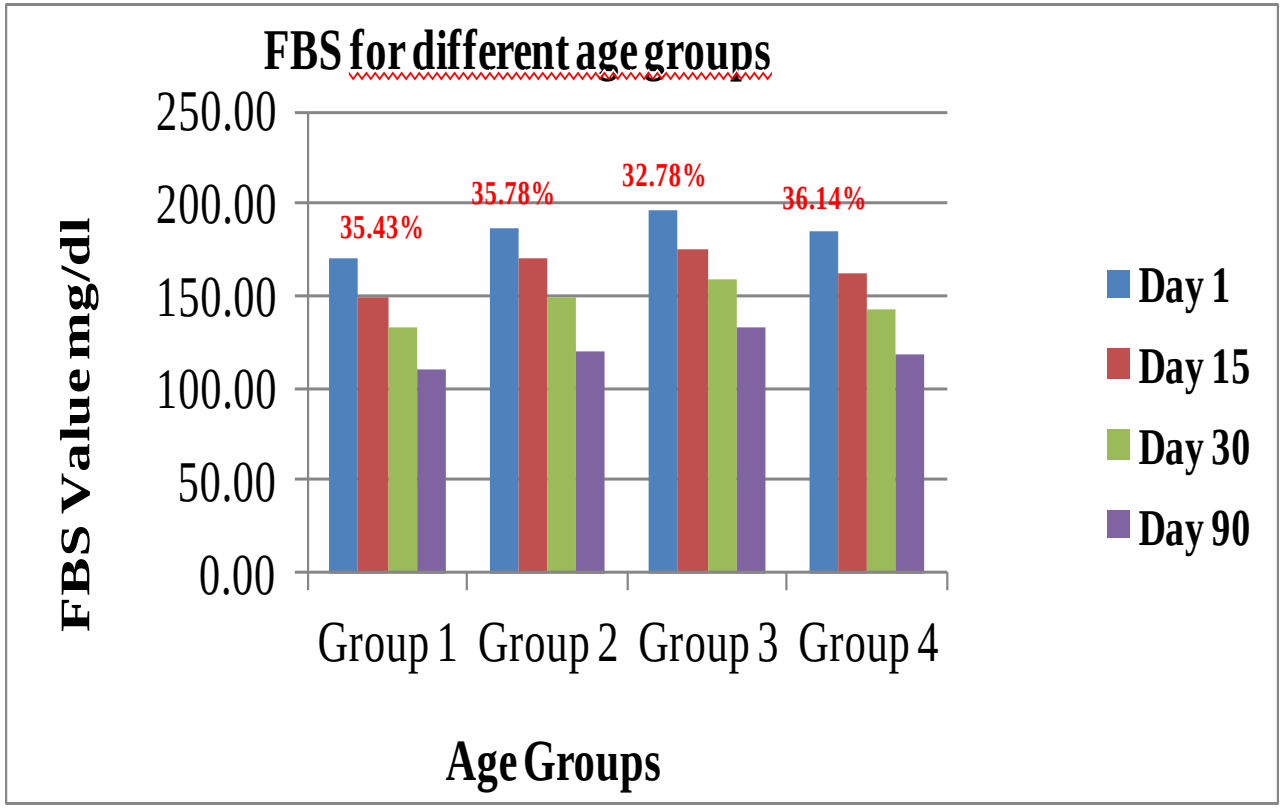
Results and Discussion *(Contd)*

2. Age wise clinical efficacy data

- FBS Data:

	Mean±SD (mg/dl)			
	Group 1	**Group 2**	**Group 3**	**Group 4**
Day 1	171.13±26.03	187.07± 30.26	196.81± 52.62	184.57± 38.11
Day 15	149.63± 20.02	170.20± 26.9	174.57± 44.20	161.86± 31.98
Day 30	132.38 ± 17.65	150.00± 25.21	158.62 ±43.44	142.71± 22.86
Day 90	110.50± 6.8	120.13± 18.49	132.29± 34.55	117.86± 15.06
% Reduction	35.43%	35.78%	32.78%	36.14%

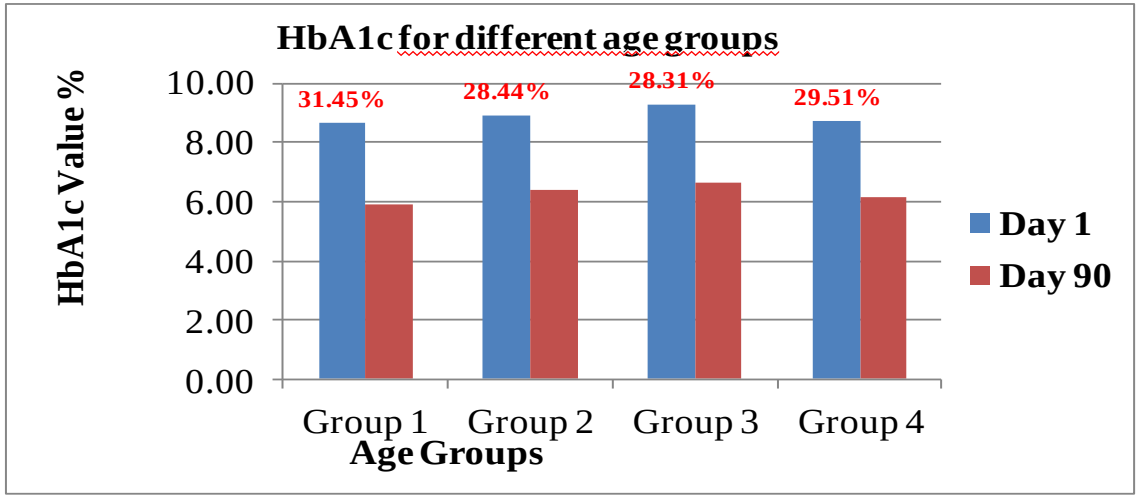
Results and Discussion *(Contd)*



Results and Discussion *(Contd)*

HbA1c data:

	Mean±SD (%)			
	Group 1	**Group 2**	**Group 3**	**Group 4**
Day 1	8.65± 0.99	8.93± 1.47	9.29± 1.99	8.71± 1.70
Day 90	5.93± 0.37	6.39± 0.75	6.66± 1.33	6.14± 0.73
% Reduction	31.45%	28.44%	28.31%	29.51%

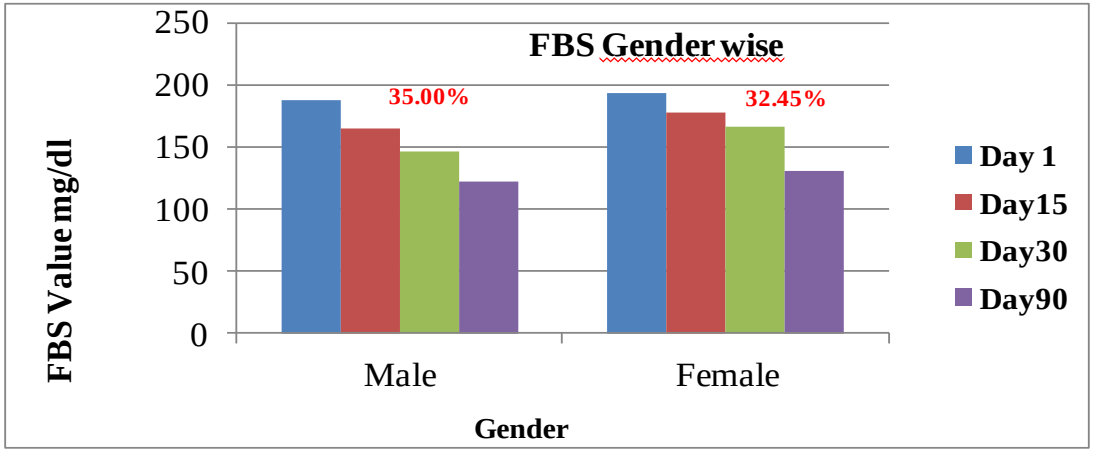


Results and Discussion *(Contd)*

3. Gender wise clinical efficacy data

- FBS data:

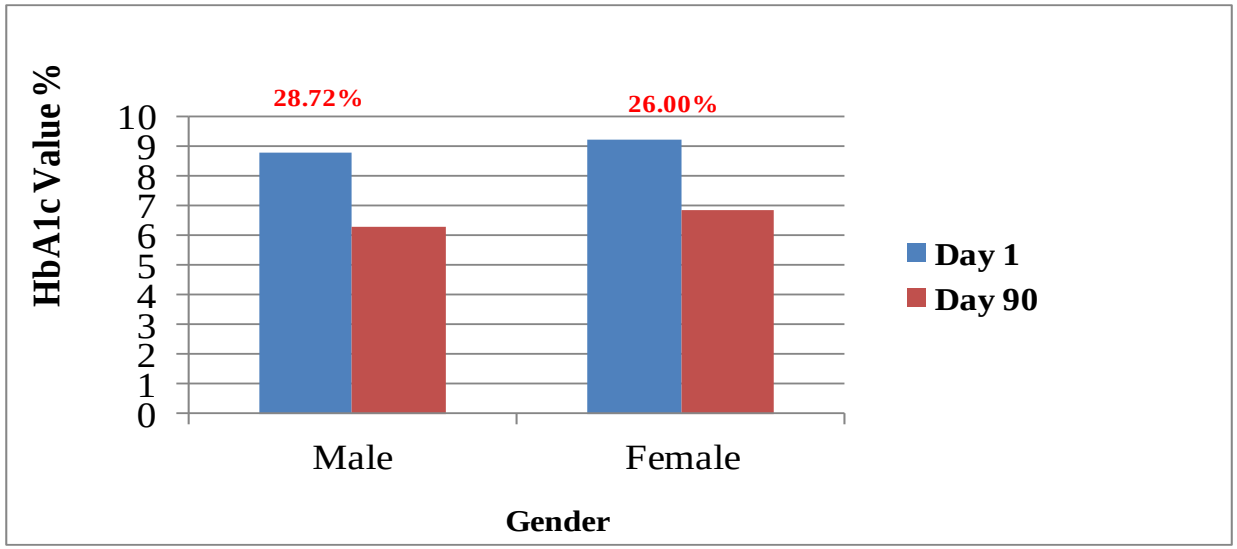
	Mean±SD (mg/dl)	
	Male	**Female**
Day 1	187.10± 42.75	192.90± 36.94
Day 15	165.00± 35.34	178.40± 34.48
Day 30	145.71± 30.59	166.50± 41.46
Day 90	121.61± 24.81	130.30± 30.69
% Reduction	35.00%	32.45%



Results and Discussion *(Contd)*

HbA1c data:

	Mean±SD (%)	
	Male	**Female**
Day 1	8.81± 1.62	9.27± 1.99
Day 90	6.28± 0.90	6.86 ±1.34
% Reduction	28.72%	26.00%

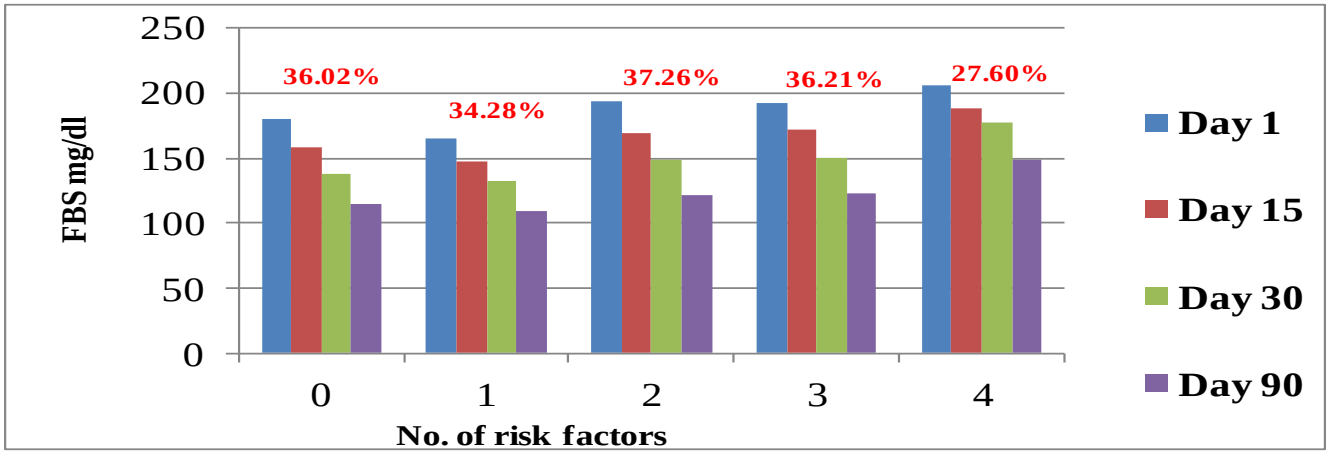


Results and Discussion *(Contd)*

4. Risk factor wise clinical efficacy data

FBS Data:

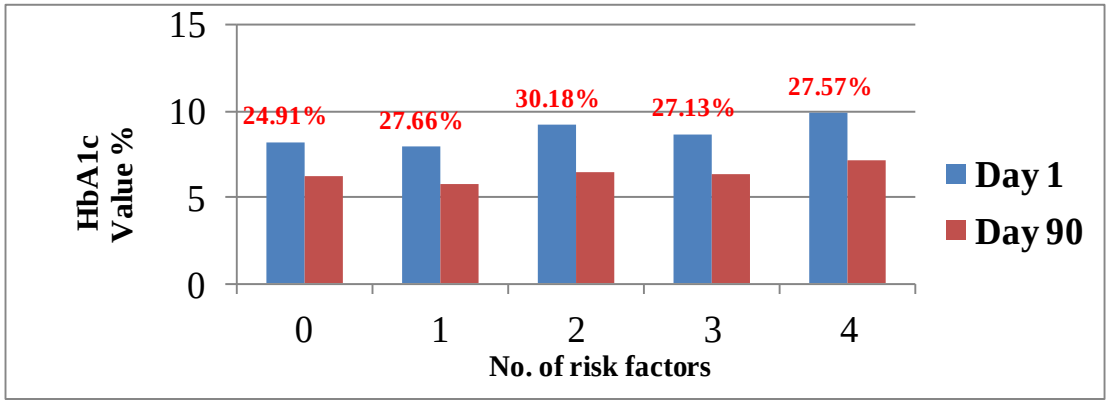
No. of risk factors	Mean±SD (mg/dl)				% Reduction
	Day 1	Day 15	Day 30	Day 90	
0	179.75± 27.65	158.25± 29.22	138.25± 27.21	115.00± 19.03	36.02%
1	165.73± 29.70	146.82± 24.02	132.36± 21.40	108.91± 10.51	34.28%
2	193.40± 35.86	169.80± 28.60	148.87± 24.00	121.33± 17.75	37.26%
3	192.17± 45.12	171.25± 30.53	150.50± 28.57	122.58± 23.47	36.21%
4	205.67± 55.88	188.78± 53.25	176.78± 52.53	148.89± 39.60	27.60%



Results and Discussion *(Contd)*

HbA1c data:

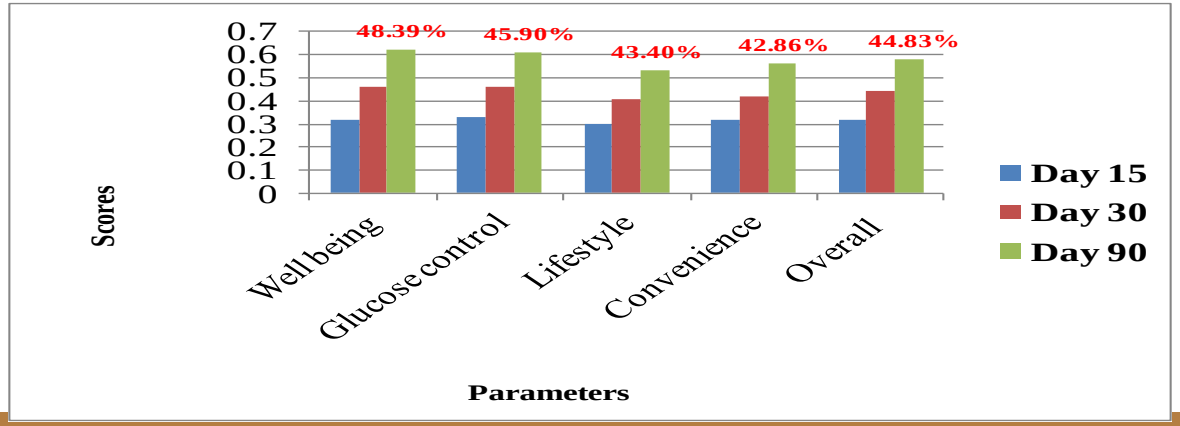
No. of risk factors	Mean ± SD (%)		% Reduction
	Day 1	Day 90	
0	8.23± 1.19	6.18± 0.92	24.91%
1	7.99± 1.55	5.78± 0.45	27.66%
2	9.21± 1.37	6.43± 0.76	30.18%
3	8.70± 1.58	6.34± 0.95	27.13%
4	9.93± 2.28	7.19± 1.56	27.59%



Results and Discussion *(Contd)*

- **Patient satisfaction results**

Parameters	Scores			% Improvement
	Day 15	Day 30	Day 90	
Well being	0.32	0.46	0.62	48.39%
Glucose control	0.33	0.46	0.61	45.90%
Lifestyle	0.30	0.41	0.53	43.40%
Convenience	0.32	0.42	0.56	42.86%
Overall	0.32	0.44	0.58	44.83%

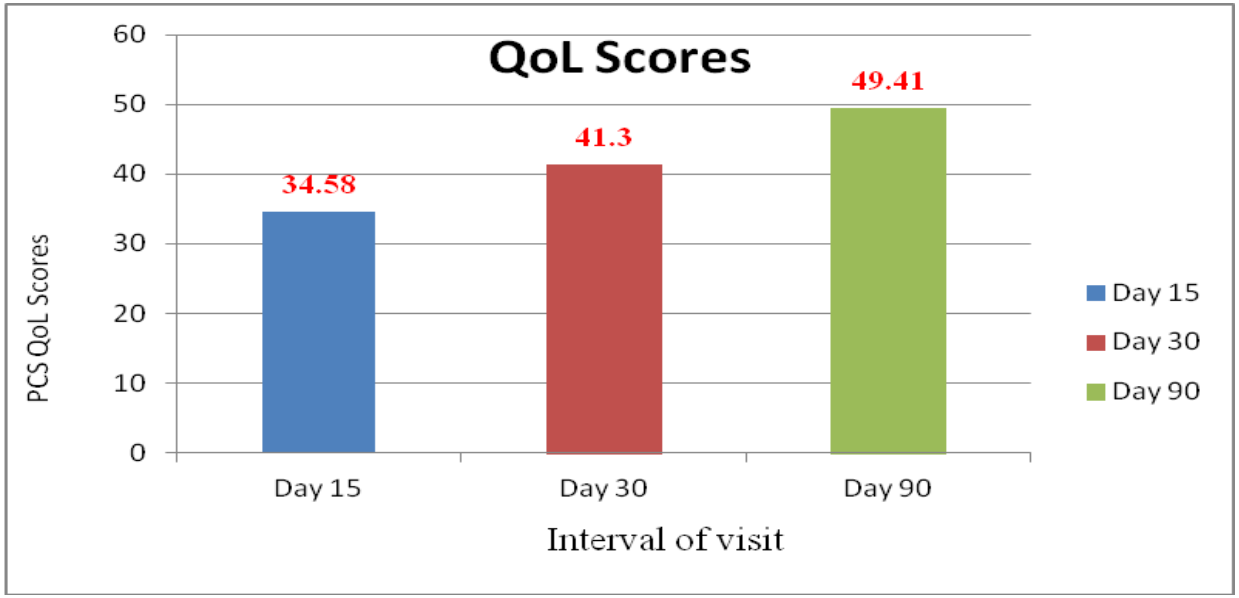


Results and Discussion *(Contd)*

- **QoL results:**

1. PCS

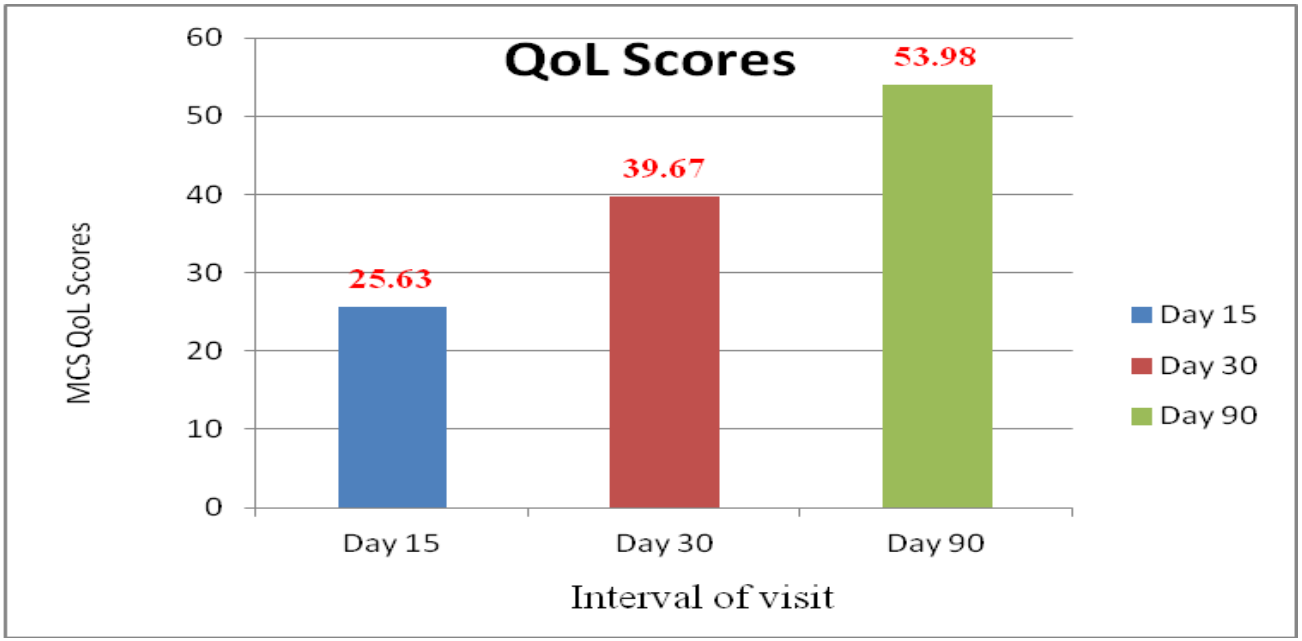
	PCS Score	% Improvement
Day 15	34.58	30.01%
Day 30	41.3	
Day 90	49.41	



Results and Discussion *(Contd)*

2. MCS

	MCS Score	% Improvement
Day 15	25.63	52.52%
Day 30	39.67	
Day 90	53.98	



Conclusion

- Increase in usage of ayurvedic medicines is one of the requirement for conducting clinical studies on ayurvedic medicines
- From this study it was found that Insol-N reduced fasting blood glucose level and HbA1c up to 40% and 30% respectively in a span of 3 months.
- Females showed lesser reduction in comparison to that of male due to lack of diet and sedentary lifestyles in female.
- Study indicates along with the diabetic therapy, risk factor management, proper diet and exercise could improve the efficacy of Insol-N.

Conclusion *(Contd)*

- The study indicates that patients were satisfied with this medication which denotes a further good relationship with the physician.
- There was improvement in both PCS and MCS components of QoL.

Points to note..

- Study was conducted only for a span of three months; another follow up of 6 months would give better results.
- Estimation of PPBS and RBS along with other risk factors like lipid profile and BP measurements could be more useful in knowing the impact of this study.
- Sample method used was non probability simple convenience method. Use of probability method would be more conclusive.
- Female ratio was too less compared to male that is 41: 10 (male: female)
- In this study only one product is used to check the clinical efficacy, similar studies with different product will be more beneficial.

References

1. Diabetes facts available at website http://www.medicinenet.com/diabetes_mellitus/article.htm (cited on 1st March 2012)
2. Diabetes risk factors available at http://www.diabetes.co.uk/Diabetes-Risk-factors.html (cited on 31st May 2012)
3. The Diabetes Medication Satisfaction Tool (DMSAT): A Focus on Treatment Regimens available at http://care.diabetesjournals.org/content/early/2008/10/17/dc08-0856.full.pdf (cited on 1st June 2012)
4. Kuppuswamy socioeconomic scale available at http://www.scribd.com/doc/18658493/Kuppuswamys-SES-Classification (cited on 1st May 2012)
5. Ayurvedic Management of diabetes mellitus at http://ayurvedam.com/pdf/ayurvdiabetes.pdf (cited on 3rd March 2012)

References *(Contd)*

6. Insol-N - An Oral Ayurvedic Anti-diabetic with a difference at http://www.ayurvedas.com/insol-n.html (cited on 8th March 2012)
7. Indian Materia Medica, by K.M.Nadakarni, volume 1 at http://books.google.co.in/books?id=RA4Npohz4CEC&pg=PR3&source=gbs_selected_pages&cad=3#v=onepage&q&f=false (cited on 20th March 2012)
8. References for raw materials- Ayurvedic pharmacopoeia of India part I, Vol I and II
9. References for preparation of Bhasmas- Ayurveda formulary of India- Part I, 18:14, PSAF Page No.46 to 58

References *(Contd)*

11. The Diabetes Medication Satisfaction Tool (DMSAT): A Focus on Treatment Regimens at http://care.diabetesjournals.org/content/early/2008/10/17/dc08-0856.full.pdf (cited on 5th April 2012)
12. SF-12v2 Health Survey available at http://www.qualitymetric.com/WhatWeDo/SFHealthSurveys/SF12v2HealthSurvey/tabid/186/Default.aspx (cited on 20th April 2012)
13. Modification of Kuppuswamy scale in context to Nepal http://www.docstoc.com/docs/48636799/Modification-of-Kuppuswamys-Socioeconomic-Status-Scale-in-context-to (cited on 3st June 2012)

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Thank You