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Research Article

A COMPARATIVE STUDY TO ASSESS THE TREATMENT COST OF AYURVEDIC MEDICINE (GINGER AND CASTOR OIL) AND MODERN MEDICINE (DMARDS) IN *AMAVATA* (RHEUMATOID ARTHRITIS)

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ABSTRACT

Ama and *Vata* are the initial elements in the pathophysiology of *Tridosha*, whereas *Amavata* is a result of their vitiation. The expense of treatment is a major factor in the economic burden of RA for both the patient and the health and social care systems. **Objective: a.** To assess the socio-demographic conditions of the patients of *Amavata*. **b.** To compare the cost of a one-month treatment of ginger and castor oil with DMARD in the management of *Amavata*. **Methodology:** Total 72 patients of RA Fulfilling the inclusion criteria and having symptoms of RA were enrolled for this Interventional study. Patients were treated in two different groups- **Group A-** 36 clinically diagnosed and registered patients of *Amavata* were treated by DMARD **Group B-** 36 clinically diagnosed and registered patients of *Amavata* were treated with ginger and castor oil. After the completion of the study, total 62 patients came after one month of treatment, so we included 62 patients in this study. 32 patients in group A and 30 patients in group B **Results:** The average direct cost of treatment of RA patients in 2024 was estimated as Rs. 2669.17 ($31.96)/month in group A (DMARD Group) and Rs. 1386.69 ($16.62) in group B (Ginger and Castor oil). Major part of total direct costs was covered by medicines (Rs. 1583) in group A and Laboratory cost (Rs. 600) in group B. The ratio of one-month cost of DMARD and Ayurvedic medicine (ginger and castor oil) was 12:1. **Discussion:** The cost of Ayurvedic medicine was very low in comparison to DMARD. Ayurvedic Medicine ginger and castor oil were easily available, safe, effective and cheap.

INTRODUCTION

Ayurvedic medicine is among the oldest forms of medicine. Among them is *Amavata*. The majority of eating practices, social structures, lifestyles, and environments have changed over time. One result of this change is the large-scale occurrence of *Amavata*. Most frequently, it occurs in patients with chronic inflammatory joint disease, which causes stiff, painful, and swollen joints. *Abhyantara and Madhyama Roga Marga*are afflicted with *Amavata,* an illness that affects *Marma, Asthi,* and *Sandhis*.

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Ama and *Vata* are the initial elements in the pathophysiology of *Tridosha*, whereas *Amavata* is a result of their vitiation. The illness worsens as a result of the aggravation (Ma.Ni. 25) reflects the equal contribution of *Dushya (Ama) and Dosha (Vata)* to the aetiology of this illness. Furthermore, because the main pathogenic causes are conflicting, it is difficult to plan the course of treatment. There are medications to treat inflammation-related symptoms, such as NSAIDS, while DMARDs provide long-term suppression. However, the majority of NSAIDs have gastrointestinal side effects, while DMARDs inhibit the liver, kidneys, and marrow.[1]

NSAIDs, or non-steroidal anti-inflammatory medicines, are currently the cornerstone of treatment for this illness; however, they have significant side effects and are not suitable for long-term use.[2] Immunosuppressive medications are only used in specific situations, and disease-modifying medications,

such as gout, are expensive and have a low benefit-to-risk ratio, necessitating the use of alternative therapy.

The expense of treatment is a major factor in the economic burden of RA for both the patient and the health and social care systems.[3] Three costs-direct, indirect, and intangible-can be measured in order to determine the cost. Expenses for doctor and healthcare provider visits, prescription drugs, diagnostic tests and procedures, and hospital stays are all considered direct medical costs. Lost productivity from absences from work, sick leaves, early retirement, etc., results in indirect costs. The term "intangible costs" refers to a patient's pain and suffering resulting from a condition. These costs are typically not included in pharmacoeconomic studies and include decreased social function, greater psychological anguish, and decreased physical function.[3,4]

One kind of pharmacoeconomic study that provides a realistic view of the financial impact of a disease condition, on both the patient and society, is the cost of therapy.[5] Pharmacoeconomics, as discussed in the World Journal of Pharmaceutical Research, focuses on treatment outcomes and costs. Numerous researches have reported on the results of RA, mostly in terms of radiographic alterations, functional impairment ratings, and mortality.[6] The primary factors that patients experience includes joint pain or stiffness, increasing economic loss based on capacity, and job loss or changes along the course of RA. Studies that describe the direct functional loss on patients' lives as well as cumulative disability and outcomes have not been widely studied. [7,8,9]

The findings of studies on the burden of disease can be utilized to establish health policy priorities and support the necessity for funding social interventions, disease management, and prevention. Since there aren't many researches of this kind conducted in north India, particularly in Eastern Uttar Pradesh, we estimated the direct medical cost and the direct non-medical cost of therapy using a cost of treatment study.

OBJECTIVES

1. To assess the socio-demographic conditions of the patients of *Amavata*.
2. To compare the cost of a one-month treatment of ginger and Castor oil with DMARD in the management of *Amavata*.

METHODOLOGY

Planning of the Study

A Hospital-based interventional study was planned to determine the socio-economic, and demographic status and comparison of treatment costs of Rheumatoid Arthritis patients in SS Hospital, IMS, BHU, Varanasi.

Research Strategy: Comparative Cross-Sectional Study

Research Setting: The study was hospital-based in the SS Hospital, IMS, BHU, Varanasi.

Diagnostic Criteria

The diagnosis of RA is based on clinical criteria, with laboratory and radiology findings helping to establish the diagnosis. The 2010 American College of Rheumatology/European League Against Rheumatism (ACR/EULAR) diagnostic criteria was applied for diagnosis as well as assessment of the trial. A patient with a score of 6 or more points out of 10 can be classified as having RA.[10,11].

Reference Population: Adult population of SS Hospital, IMS BHU.

Study Population: Adult subjects attending the Rheumatology OPD and Kaychikitsa OPD of SS Hospital, IMS, BHU, Varanasi, were diagnosed as a case of *Amavata* (RA).

Inclusion Criteria

1. Adult population of age group 18-60 years attending rheumatology OPD, suffering from rheumatoid arthritis.
2. Patient with duration of disease not more than two years.
3. Patients with rheumatoid arthritis with mild to moderate disease.
4. Patients of rheumatoid arthritis without any systemic complications.

Exclusion Criteria

1. Patient having co-morbidity like diabetes mellitus.
2. Patient having pregnancy.

Sample Size

Sample Size (n) = $\frac{(z1-\alpha+Z1-\beta)2[p1(1-p1)+p2(1-p2)]}{[d-(p1-p2)]2}$

- Anticipated event rate during a fixed period in standard treatment group = p_1
- Anticipated event rate during a fixed period in new treatment group = p_2
- Maximum clinical difference allowed for standard treatment considered to be non-inferior =d
- Value of the normal deviate at considered level of confidence= $z_{1-\alpha}$ (one-sided test)
- Value of the normal deviate at considered power of the study= $Z_{1-\beta}$

P1= 45%, p2= 65%, $z_{1-\alpha}$= 1.64, $Z_{1-\beta}$ = 0.842, d = 10 %, α = 5%, β = 80 %

$$N=\frac{(1.645+0.842)^2[0.45(1-0.45)+0.65(1-0.65)]}{[0.10-(0.45-0.65)]^2} = 32.51\ (33)$$

Considering 10% loss to follow up

N=33+3= 36

Hence,

Total Sample Size (N) =36×2=**72**

Study Profiles

1. Demographic Profile

2. Treatment Cost Profile

Study Design and Treatment Schedule

In the present study sample size was 72 but after the completion of the study, total 62 patients came after one month of treatment, so we included 62 patients in this study. 32 patients in group A completed all follow-up and 30 patients in group B completed all follow-up. The cases were randomly allocated regardless of their age, sex, and religion. All 62 patients were recruited randomly on numbering methods into two groups, as below-

Group A: 32 clinically diagnosed and registered patients of RA were treated by-

DMARD's

(1) Methotrexate: 2.5mg tab OD orally – 90 days.
(2) Hydroxychloroquine: 200mg tab BD orally- 90 days.
(3) Sulfasalazine: 1000mg tab BD orally- 90 days.
(4) Leflunomide: 10mg OD tab orally- 90 days

Group B- 30 clinically diagnosed and registered patients of RA were treated by

(1) Ginger Powder (Zingiber Officinal): 2gm, thrice a day with normal water.

(2) Castor Oil (Ricinus Communis): 10ml once after dinner with lukewarm milk.

(For 90 days with follow-up of a 1-month interval)

Intervention

There will be two groups of study subjects for this Study. Group-1 will receive the standard treatment Group-2 will receive the drug intervention.

Study Measurement

Pre-Designed questionnaire

Cost was mainly divided into two parts-

1. Direct medical Cost
2. Direct Non-Medical Cost

Data Analysis[12,13]

The data collected had been transferred to master chart showing various items/variables in columns and subjects in rows. The analysis of data was done using statistical software SPSS 25.

The items on demographic profile and personal characteristics were summarized using univariate and bivariate frequency tables, percentage, graphs and for continuous variables mean, ratio and standard deviation (SD) were determined.

The formulae for mean and standard deviation are given as below:

Mean $= \frac{\Sigma x}{n} = \frac{\sum of\ t\ eobservations}{No.of\ t\ eobservations}$

Standard Deviation SD= $\sqrt{\ }$

Inter-group comparison (Between the groups)

To test the significance of difference of means of two independent groups, **unpaired t test (independent sample t test)** was applied.

$t = \frac{M_1 - M_2}{\sqrt{\ }}$

Where, M_1 = Mean of Group 1, M_2 = Mean of Group 2

$S^2 = \frac{\Sigma {x_1}^2 - \frac{(\Sigma x_1)^2}{n_1} + \Sigma {x_2}^2 - \frac{(\Sigma x_2)^2}{n_2}}{n_1 + n_2 - 2}$

Here, d.f. = $n_1 + n_2 - 2$

Corresponding to t value, p-value was determined.

Wherever, the data did not satisfy the assumptions of parametric test, non-parametric test viz., Mann-Whitney U test was applied.

Statistical Significance

$p < 0.05$ considered as statistically significant

$p < 0.01$ or $p < 0.001$ as highly statistically significant

$p > 0.05$ not statistically significant.

RESULT

In the present study sample size was 72 but after the completion of the study, total 62 patients completed all 3 follow-ups, so we included 62 patients in this study. 32 patients in group A completed all follow-up and 30 patients in group B completed all follow-up.

A. Socio-Demographic profile

Table 1: **Assess the Socio-Demographic Status of RA patients within two groups. (DMARD vs Ginger and Castor Oil)**

Age (In Years)	Group A (DMARD)		Group B (Ginger and Castor Oil)		Total	
	No.	%	No.	%	No.	%
18-30 Years	13	40.6	5	16.7	18	29.03
31-40 Years	8	25.0	9	30.0	17	27.41
41-50 Years	8	25.0	9	30.0	17	27.41
51-60	3	9.4	7	23.3	10	16.12
Gender						

Male	8	25.0	8	26.3	16	25.80
Female	24	75.0	22	73.7	46	74.19
Marital Status						
Married	25	78.1	25	83.3	50	80.64
Unmarried	7	21.9	5	16.7	12	19.35
Habitat						
Urban	10	31.3	12	40.0	22	35.5
Rural	22	68.8	18	60.0	40	64.5
Education						
Illiterate	9	28.1	1	3.3	10	16.1
Literate	5	15.6	3	10.0	8	12.9
Primary	2	6.3	3	10.0	5	8.1
Middle	3	9.4	5	16.7	8	12.9
High School	0	0.0	1	3.3	1	1.6
Intermediate	4	12.5	1	3.3	5	8.1
Graduate	5	15.6	10	33.3	15	24.2
Postgraduate	4	12.5	6	20.0	10	16.1
Occupation						
Farmer	1	3.1	1	3.3	2	3.2
Labour	1	3.1	0	0.0	1	1.6
Business	1	3.1	1	3.3	2	3.2
Service	3	9.4	5	16.7	8	12.9
Housewife	20	62.5	19	63.3	39	62.9
Student	6	18.8	4	13.3	10	16.2

The study of age among 62 patients of *Amavata,* reveals that the maximum patients belonged to the age group 18-30 years having 18 (29.03%) patients followed by 31-40 years and 41-50 years (27.41%). Majority of patients were female (74.19%); both in group A (75.0%) and B (73.7%). This indicates that *Amavata,* is more common in female then male which is comparable with prevalence of RA in current scenario. About 4 out of 5 patients (80.64%) patients were married. Majority of patients (64.5%) belonged to rural habitat. Table- 1 indicates that out of 62 patients, 15 (24.2%) were graduate and 10 (16.1%) were illiterate and postgraduate. Primary and middle level educated were 5 (8.1%) and 8 (12.9%) respectively. Majority of patients i.e., 39 (62.9%) were Housewife, followed by Student (16.2%) and Service (12.9%)

Table 2: Distribution of RA patients within two groups according to Per Capita Income (per month) According to B G Prasad's Classification (Rs/month)

Income	Group A		Group B		Total	
	No.	%	No.	%	No.	%
7700& above	6	18.8	11	36.7	17	27.4
3808-7769	18	56.3	16	53.3	34	54.8
2253-3808	5	15.6	3	10.0	8	12.9
1166-2253	3	9.4	0	0.0	3	4.8
1166 & above	0	0.0	0	0.0	0	0.0
Total	32	100.0	30	100.0	62	100.0

Table-2 shows that out of 62 patients' maximum number of patients i.e., 34 (54.8%) belonged to category 3808-7769 whereas 17 (27.4%) belonged to category 7700 & above.

B. Treatment Cost profile

Table 3: Distribution of RA patients with in two groups according to Direct Medical Cost of Treatment

Particulars	Group A		Group B		Ratio (B: A)
	Cost	%		%	
Medicine Cost	1583.00	72.59	131.00	17.21	1: 12.08
Laboratory Cost	567.75	26.03	600.00	78.77	1: 0.94
Hospital Registration Cost	30.00	1.37	30.00	3.93	1:1
Total	2180.75	100.00	761.66	100.00	1: 2.86

Fig 1: Treatment Cost of RA Patients in group B

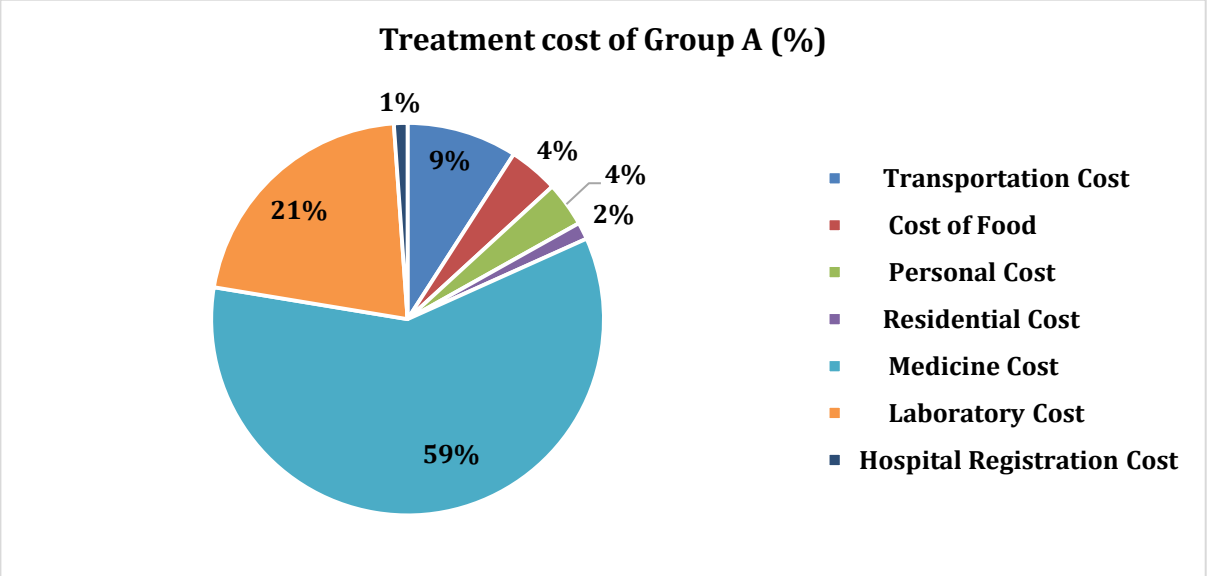

Fig 2: Treatment Cost of RA Patients in group A

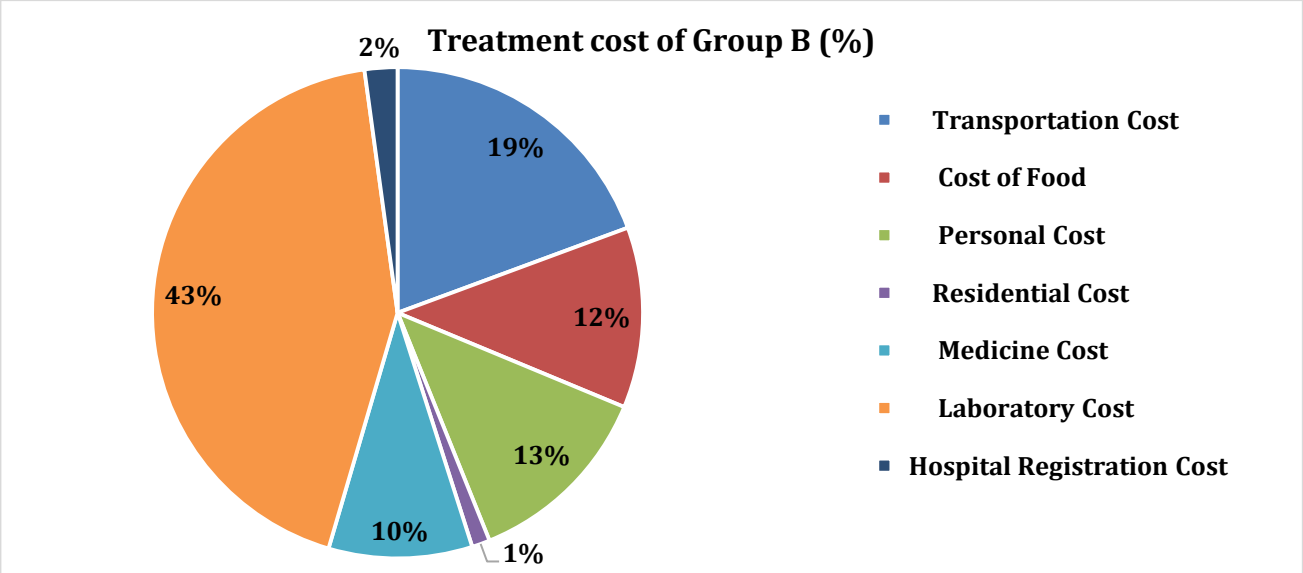

Table 4: Distribution of RA patients with in two groups according to Direct Non-Medical Cost of Treatment

Particulars	Group A		Group B		Ratio (B: A)
	Cost	%	Cost	%	
Transportation cost	243.12	49.77	268.33	42.93	1: 0.90
Cost of food	109.37	22.39	165.00	26.40	1: 0.66
Personal cost	98.43	20.15	175.00	28.00	1: 0.56
Residential cost	37.50	7.67	16.6	2.65	1: 2.25

Total	488.42	100.00	624.93	100.00	1: 0.78

Table 5: Distribution of RA patients with in two groups according to Total Direct Cost of Treatment

Particulars	Group A		Group B		Ratio (B: A)
	Cost	%	Cost	%	
Direct Medical Cost	2180.75	81.70	761.66	54.93	1: 2.86
Direct Non-Medical Cost	488.42	18.29	624.93	45.06	1: 0.78

Table -3, 4 and 5 presents that, total average direct cost per month for treatment of RA was found to be Rs. 2669.17 in group A and Rs.1386.69 in group B. In group A- Major part of total cost was covered by medicine cost (Rs.1583.00) and followed by laboratory cost (Rs. 567.75) and Transportation Cost (Rs. 243.12), whereas in group B- Major part of total cost was covered by Laboratory cost (Rs. 600.00) and followed by Transportation cost (Rs. 268.33). The ratio of one-month Total cost of Group B- Ayurvedic medicine (ginger and castor oil) and Group A- modern Medicine (DMARDs) was 1: 2.86.

Table 6: Total Cost/ Month medicines used in treatment of RA (Group A)

Medicine	No. of Patients	Unit Price (Rs)	Cost of Drug/ Day (Rs)	Cost of Drug/ Month (Rs)	% Drug cost/ Month
Methotrexate 2.5 mg (OD)	32	5.02	5.02	150.60	9.51
Sulfasalazine 1000mg (BD)	32	11.60	23.21	696.30	43.98
Hydroxychloroquine 200mg (BD)	32	6.66	13.33	399.90	25.26
Leflunomide 10mg (OD)	32	11.20	11.20	336.00	21.22
Total			52.77	1583.00	100.00

Table 7: Total Cost/ Month medicines used in treatment of RA (Group B)

Medicine	No. of Patients	Unit Price (Rs)	Cost of Drug/ Day (Rs)	Cost of Drug/Month (Rs)	% Drug cost/ Month
Ginger (2gm TDS)	30	0.31	1.86	55.80	42.59
Castor Oil (OD)	30	.25	2.50	75.00	57.25
Total			4.36	131.00	

Table 6, 7 presents that medicine cost/month in group A was 1583.00, whereas medicine cost/month in group B was 131.00. Among the DMARDs, monthly cost was high for sulfasalazine (Rs. 696.30) followed by hydroxychloroquine (Rs. 399.90) and leflunomide (Rs. 336.00). Sulfasalazine consumes about 43.98% of drug cost per month followed by hydroxychloroquine (25.26%) and leflunomide (21.22%). Among The Ayurvedic medicine, monthly cost of ginger was Rs.55.80 and castor oil was Rs. 75.00, which is a little more than monthly cost of ginger. Castor oil consumes about 57.25% of drug cost per month followed by ginger (42.59%). The result indicates a marked difference in monthly cost of Ayurvedic medicine (ginger and castor oil) as compared to modern medicine (DMARD) (1:12.08).

Table 8: Comparison of Medicine Cost between Group A (DMARD) and Group B (Ginger and Castor Oil)

Group	Medicine Cost		Between group comparison **(Independent t- test)**
	Mean	**SD**	
Group A (n=32)	1583.00	0.00	t= 43561.00
Group B (n=30)	130.97	0.18	p= 0.00

Table 8 shows the descriptive statistics of both group A and B. The p- value of the *Independent t- test* is 0.00, which is highly significant. This finding concludes that medicine cost in group B (Ayurvedic Medicine Group) is very low in comparison to medicine cost of group A.

DISCUSSION

The aim of this study was mainly to compare the one-month cost of Ayurvedic medicine (ginger and castor oil) and modern medicine (DMARDs) on the treatment of *Amavata* (RA). According to this study, the average cost of treatment with RA was estimated to be Rs. 2669.17/month in group A (DMARDs) and Rs.1386.69/month in group B (ginger and castor oil). Cost was mainly divided into two parts- Direct medical cost and direct nonmedical cost. Total direct medical cost was estimated to be Rs. 2180.75/month in group A, in which medicine cost covered Rs.1583.00 (72.59%) and followed by laboratory cost Rs. 567.75 (26.03%). Total direct medical cost was estimated to be Rs.761.66 /month in group B, in which Laboratory cost covered Rs. 600.00 (78.77%) and followed by Medicine Cost Rs. 131.00 (17.21%). Direct Medical Cost in group A was just triple to direct medical cost in group B. The ratio of one-month cost of DMARDs and Ayurvedic medicine (ginger and castor oil) was 12:1.

Total direct non-medical cost was estimated to be Rs. 488.42/month in group A, in which transportation covered maximum cost Rs. 243.12 (49.77%) and followed by Cost of food Rs. 109.37 (22.39%) and Personal cost Rs. 98.43 (20.15). Total direct non-medical cost was estimated to be Rs. 624.93 /month in group B, in which transportation covered maximum cost Rs. 268.33 (42.93%) and followed by Personal cost Rs. 175.00 (28.00) and cost of food Rs. 165.00 (26.39%). Direct non-medical cost was almost similar in both groups. The transportation cost varied among individuals due to distance travelled and mode of transportation. Monitoring of clinical variables was necessary to determine the effectiveness of the treatment and to rule out side effects. ESR, HB, LFT, RFT and CRP were done at timely intervals. They varied with disease intensity and duration. In this study most of the patients were unemployed housewives (62.5 % in group A and 63.3% in group B).

Study conducted by Peter Tug well et al in USA and Canada, they found that DMARDs were most commonly prescribed category of drugs.[14] The same was observed in study conducted by Shini et al., in Kerala and also in our study. [15]

The result of US based study showed the mean total annual direct medical cost for RA patient was $9,519 in 2001. Medicine cost was $6,324 (66% of the total), while hospitalization cost was only $1,573 (17%). Approximately 25% of patients received biological therapy. The mean total annual direct cost for patient who was not taking biological was $ 6,164. Per month cost was calculated as $513.66.[16] This is higher than our direct cost which is about $31.96 per month. The discrepancy of annual cost of RA might be due to the difference in health care systems, referral practices, financing, GDP, and methodologies of studies between India and other countries.

A study on RA patients in Kochi showed the total direct cost Rs 1929.99/month which is a little lower to our study (Rs.2669.17). [17] This may be due to difference in period of time, the studies were conducted. If we compare the medicine cost of DMARD and Ayurvedic medicine (ginger and castor oil) then one-month cost of DMARD was estimated to be Rs. 1583.00 whereas one moth cost of Ayurvedic medicine was found to be 131.00. The cost of Ayurvedic medicine was very low in comparison to DMARD. In this study most of the patients were unemployed housewives, so females depend on her husband for the treatment, but ginger and castor oil were easily available, safe, effective and cheap. As its plant can be grown in the kitchen garden or in the road side, its popularity and ease of use in the rural area may be a boon for villagers.

CONCLUSION

This study has some limitations. First, a limited number of patients were included in the study and for a short duration. The study focuses exclusively on Conventional Synthetic DMARDs for RA treatment instead Biologic DMARDs and Targeted Synthetic DMARDs. Even though, this study, not only can decrease the economic burden on the health care system, but also can get rid of limiting adverse events of DMARDs. Due to increase in the public interest, there is a need to research more herbal medicines and development of suitable effective formulations which could be very safe, easy to take, cost effective and beneficial for rheumatoid arthritis and other inflammatory disorders.

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