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An Open Labelled Randomized Controlled Parallel Group Clinical Study to Evaluate the Efficacy of *Prasarini Sandhanam* in Management of Rheumatoid Arthritis

Ramyashree Nagendra[1] , Gopala Krishna G[2] ,

1- Assisstant professor, Department of Kayachikitsa, KTG Ayurvedic medical college, Bengaluru
2- HOD, Department of Kayachikitsa, Sri Sri College of Ayurvedic science and Research, Bengaluru

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Corresponding author-
Ramyashree Nagendra , Assisstant professor, Department of Kayachikitsa, KTG Ayurvedic medical college, Bengaluru

Email: ramyashreenagendra@gmail.com

ABSTRACT:

Introduction: Rheumatoid Arthritis (RA) is a chronic inflammatory disease of unknown aetiology marked by a symmetric, peripheral polyarthritis. The prevalence of Rheumatoid arthritis is approximately 0.8 – 1.0 % in Indian subcontinent, with female to male ratio of 3:1. In *Ayurveda*, *Amavata* can be co-related to Rheumatoid arthritis based on its clinical signs and symptoms. *Mandagni* (hypo functioning of digestive fire) and derangement in *Vata* (vital force of the body) results in manifestation RA.
Aims and Objectives: To evaluate the efficacy of *Prasarini Sandhanam* (PS) and *Simhanada Guggulu* (SNG) and compare their efficacies in management of Rheumatoid Arthritis.
Materials and methods: In the present study 32 patients were enrolled and the study was completed in 30 patients. The patients were allocated randomly in two groups. Group A was administered with *SNG* (control group) while Group B was administered with *PS* (trial group).
Results: The effect of treatment on 30th day has shown statistically significant result in group A with p value <0.05 in parameters like pain, stiffness, swelling and warmth in the joints, general signs and symptoms and degree of disease activity score. The effect of treatment in group A did not show statistically significant result in General functional capacity, tenderness in joints and Quality of life of patients through Barthel's index score with p value > 0.05. On follow up all parameters did not show statistical significance with p value > 0.05. The effect of PS in group B on 30th day have shown statistically highly significant result with p value <0.01 in all parameters whereas on follow up it did not show statistically significant result with p value > 0.05 in all parameters. On comparison, Group B have shown better results than Group A in all the parameters.
Conclusion: Both the groups showed statistically significant results but on comparison group B (PS) showed better results than group A (SNG). By the virtue of its aetiology, pathogenesis, clinical signs and symptoms and management, Rheumatoid arthritis bears close resemblance to *Amavata* and can be tackled effectively on the lines of its management as mentioned in classics.
Keywords: *Prasarini sandhanam*, *Simhanada guggulu*, *Amavata*, Rheumatoid Arthritis

INTRODUCTION

Present days fast lifestyle, irregular sleep patterns and disorganized diet practices have caused increase in the growth of many metabolic and autoimmune diseases in society. One of the common autoimmune diseases prevailing in the population is Rheumatoid Arthritis (RA).[1] It is a chronic inflammatory disease of unknown aetiology marked by a symmetric, peripheral polyarthritis. It is the most common form of chronic inflammatory arthritis and

often results in joint damage and physical disability. [2] The prevalence of Rheumatoid arthritis is approximately 0.8 – 1.0 % in Indian subcontinent, with female to male ratio of 3:1.[3] Chronicity of disease results in very poor quality of life where a person is unable to do his/her routine activities and lead an independent life. Treatment given in contemporary science mainly includes NSAID'S, cortico-steroids and DMARD (Disease Modifying Anti-rheumatoid drugs), which results in many complications on a long run.[4] In *Ayurveda*, *Amavata* can be co-related to Rheumatoid arthritis based on its clinical signs and symptoms. Hypo-functioning of digestive fire hampers the normal digestive metabolism and forms *ama* (improperly digested or unwanted substances to the body like free radicles) which becomes basis for manifestation of all diseases.[5] *Vata* being the vital force of life is responsible for every metabolism in the body. Derangement in the functioning of *Vata* along with accumulated toxic substances within the body results in manifestation of RA.[6] Since pain is the predominant symptom caused due to inflammation, RA becomes more serious condition which needs an effective pain management with stoppage of inflammation and further destruction of joints. Although many research works are done in this area, still the quality of life of patients suffering from RA is not satisfactorily appreciated. Hence this becomes the area of scope for further studies for an effective and safe management of RA.[7] In the light of *Ayurveda*, the present study is planned using PS mentioned in the chapter of *Amavata* in treatise *Chakradatta*. SNG mention in the same chapter is considered as control drug.[8]

OBJECTIVES

To evaluate the efficacy of *Prasarini Sandhanam* and *Simhanada Guggulu* and compare their efficacies in management of Rheumatoid Arthritis.

MATERIALS AND METHODS

Study Design

It is an open labelled randomized controlled parallel group clinical study. The study was approved by institutional ethical committee on 27/03/2019 (SS/EC/64/2019). The Clinical Trial has been registered in Clinical Trial Registry of India (CTRI/2020/04/024674). Randomization was done using Coin toss method.

Study Participants

The study was conducted on subjects with signs and symptoms of RA attending the OPD and IPD of Sri Sri College of Ayurvedic Science and Research Hospital. 32 patients fulfilling the inclusion and exclusion criteria were randomly selected in the age group of 21-70 years irrespective of gender, religion, economic status and occupation. They were allocated into two groups of 17 patients in Group A and 15 patients in Group B. Out of them 30 patients completed the study with 2 dropouts in Group A.

Sample size estimation

Due to practical and time constrains and academic purpose, a minimum of 32 samples were taken for the present study. Due to 2 drop-outs, 30 samples were considered for statistical analysis.

CTRI Registration No

The present study was registered under CTRI with the registration No: REF/2020/01/031127

Inclusion criteria

Subjects belonging to age group 21-70 years, willing to give informed consent for research, subjects who satisfy 4 criteria out of 7 of ARA criteria (1987), subjects with classical signs and symptoms of RA.

Exclusion criteria

Subjects with age group <21 and > 70 years, subjects suffering from Rheumatoid arthritis secondary to any systemic diseases, who have complications like swan neck deformity, ulnar deviation and any other diseases which interfere with the course of disease and treatment will be excluded.

Subjective parameters

Pain, stiffness and swelling in the joints[9], general signs and symptoms of RA like pain all over body, loss of taste perception, excessive thirst, lethargy, heaviness of the boby, pyrexia, indigestion, stiffness of the body, general debility, heaviness in chest region, inflammation of joints[10] were considered as subjective parameters for assessment.

Objective parameters

The objective parameters considered were, Tenderness in the Joints, Warmth in the joints, Degree Of Disease Activity Score, General Functional Capacity[11] and Barthel's Index Score for assessing Quality of Life.

Grouping (Flow chart 1)

In the present study, 32 patients were registered for the clinical trial. The patients were randomly allocated to both the groups with 17 patients in Group A and 15 patients in Group B. 30 patients completed the study and 2 drop outs were present.

Intervention (Table 1)

In the present study, group A is taken as controlled group and administered with SNG in the dosage of 2 TID after

food with adjuvant of warm water for 30 days. Group B is taken as trial group and administered with PS in the dosage of 15ml TID after food with warm water as adjuvant for 30 days. Follow up was done for 15 days.

Drug Source

The ingredients of trial medicine PS were obtained from the Sri Sri herbal garden and SNG was procured from GMP certified pharmacy. PS was prepared in teaching pharmacy of Department of *Rasashastra* and *Bhaishajya Kalpana* on 19/12/2019. Packaging was done on 5/2/2020.

Method of preparation of *Prasarini sandhanam*

PS is having *Paederia foetida* Linn.,[12] *Allium sativum* Linn.[13] and powder combination of *Panchakola* (*Piper longum* Linn., *Piper chaba* Hunter, *Plumbago zeylanica* Linn., *Zinziber officinale* Roscoe) in *Arishta* form (medicine which is prepared from decoctions of drugs and contains self- generated alcohol). Quantity of drugs used for preparation are mentioned in (Table 2).

P. foetida whole plant was collected and it was washed thoroughly and cut into smaller pieces.

Later the pieces were crushed coarsely with mortar and pestle. To the crushed drug 60 liters of water was added according to the ratio of decoction preparation (1:4).[14] It was boiled on low fire till it reduced to one fourth (15 liters) and was allowed for self-cooling. Decoction was filtered and it was transferred to vessel where medicine is kept for fermentation after its fumigation. Jaggery was crushed and made into Gudapaka (jaggery melted in water through boiling). *A. sativum* was cleaned and crushed coarsely with mortar and pestle. Both jaggery (2 kgs) and *A. sativum* (2kgs) were added to the decoction and mixed thoroughly. *Panchakola* powder was added and mixed completely. Vessel was closed with the lid and sealed. It was placed in the heap of husk for fermentation. After attaining the qualities of proper fermentation medicine was filtered and packed with 200ml bottles.

Dietary advices and lifestyle modification

Diet was advised to be light, freshly prepared, hot and light for digestion. Timely intake of food and intake only in the presence of hunger was advised. Patients were advised to take warm water processed with ginger and cumin seeds. Patients were asked to avoid, heavy foods, curd, non-vegetarian foods, intake of cold water, exposure to cold wind and day sleep.

Laboratory Investigations

Hb% and ESR were assessed in the patients as it is a part of Degree of Disease activity score. RA test was not considered as both positive and negative for RA test was included for study. CRP was done only in few patients due to practical constrains and is mentioned as the limitation of the study.

Assessment Criteria

Assessment was done on 0^{th}, 15^{th}, 30^{th} and 45^{th} day (Follow up) during the study duration. Gradings were used for assessment of subjective and objective parameters (Table 3 – 10). Pain was assessed using VAS scale. Barthel's index score was used for assessment of Quality of life (Figure 2) and Degree of disease activity score was used for assessment of severity of disease.[12]

Statistical analysis

In the present study, non-parametric values like pain, swelling, stiffness, tenderness, warmth in the joints, General functional capacity, Barthel's index score and general signs and symptoms were analysed using Mann – Whitney U Test for between the groups and Wilcoxon signed rank test for within the groups. Parametric value like Degree of Disease Activity Score was analysed using unpaired t-test between the groups and Paired t-test within the group. The corresponding p value was noted and obtained results were interpreted as insignificant for p value >0.05, significant for p value <0.05 and highly significant for p value <0.01.

Outcome

Primary: Pacifying the symptomatology of Rheumatoid Arthritis. Secondary: Due to reduction in the signs and symptoms of RA, drugs may also help in improving the quality of life of the patients.

OBSERVATIONS AND RESULTS

Demographic profile

The prevalence of disease was majorly seen between the age groups of 56 – 65 years. (33.33%). Prevalence was more in females (76.66 %)than males. Housewives (56.09) showed a high prevalence in the present study followed by jobs related to agriculture and business.56.6% of the patients in the study belonged to Middle class and 23.30% of patients belonged to lower middle class. 20% of the patients belonged to the upper middle class strata. 96.60% of the patients were married while only 3.3% were unmarried.

In the present study 53.3% of the patients were graduates 20% of patients had completed secondary schools. 26.6% of patients had attended primary school. About 63.30% of the patients were said to have a moderate type of physical activity daily followed by 30% having vigorous form of activity daily. 36.6% of patients were overweight and

obese, 26.6% were having normal Body mass Index. In the present study 25 patients (83.3%) were found to have hypo functioning of metabolic fire. In the present study 27 patients (90%) and 24 patients (80%) were having stress and day sleeping respectively as a common cause.

In the present study 73.30% of patients belonged to area with moderate climatic conditions and 46.60% belonged to area with dry climate and 10% of patients belonged to area with humid climate). 36.6% presented with a known history of Rheumatoid arthritis since 1-5 years, 26.6% presented with a positive history of RA since less than 6 months, 20% presented with a history of RA since 6 months – 1 year and 16.6% of patients reported to have the same since more than 5 years.

Effect of Medications:

Within group A, the effect of treatment (SNG) on 30th day has shown statistically significant result with p value <0.05 in **pain, stiffness and swelling in the joints, warmth in the joints, general signs and symptoms** and **degree of disease activity score**. The effect of treatment in group A did not show statistically significant result in **general functional capacity, tenderness in joints** and quality of life of patients through **Barthel's index score** with p value > 0.05. On follow up all parameters did not show statistical significance with p value > 0.05.

Within group B, the effect of treatment (PS) on 30th day have shown statistically highly significant result in all subjective and objective parameters with p value <0.01, whereas on follow up it did not show statistically significant result in any parameter with p value > 0.05.

On comparing the values between the groups on 30th day (After treatment) and on follow up (Table 11-19) group B (PS) showed better results than group A (SNG) with statistically highly significant result in all subjective and objective parameters with p value <0.01.

DISCUSSION

In the present study, stress was the most common factor observed in all the subjects followed by practice of day sleep. Many research studies have proved that stress is identified as a major trigger for manifestation of auto-immune conditions like Rheumatoid Arthritis.[15] Practice of regular day sleeping results in *tridosha prakopa (vitiation of all three life humour's)* which hampers the proper digestive metabolism (even the correct quantity of food taken will not be digested).[16] This undigested material on further stagnation acts as a toxic substance to the body and releases many free radicles and pro inflammatory markers. This further activates the Antigen presenting cells (dendrites and macrophages) which continues the inflammatory cascade resulting in destruction of joints.[17]

Majority of patients were habituated to untimely intake of food and intake of food items which are heavy and which do not undergo proper digestion. This results in accumulation of toxins and thus triggers the autoimmune response. Hence the above lifestyle and diet practices can be considered as causes resulting in manifestation of RA.

Probable mode of action of trial drug:

This *yoga* possesses properties of pacifying *Vata* and *Kapha doshas*, increasing the digestive metabolism by acting on digestive fire, removing the toxic substances from the body and clearing the microchannels.[18] It causes liquification of accumulated *kapha* and hence removes the obstruction caused by it to the movement of Vata. By this Vata which is the vital energy in the body starts flowing in the proper direction. Both *Vata* and *Kapha* which would have accumulated in joints is removed thereby reducing the inflammation.[19] This might have helped in reducing the swelling and stiffness in the joints effectively. A. *sativum* and *P. foetida* have analgesic properties which helps in reducing the pain and tenderness in the joints.

The *Arishta* form of the medicine also helps in improving the digestion and assimilation as it has the ability to enter the cellular level and micro circulation due to the presence of self- the therapeutic properties, which may be due to the microbial biotransformation. It also helps in improving the bio-availability and drug delivery in the body.[20] All the above properties said helps in pacifying the *Kapha Dosha*, bringing *Vata* to its normalcy thereby correcting the digestive impairments which is the basic pathology of the disease.The oxidative stress caused by free radicles can be considered as one of the causes for triggering the auto immune response and inflammatory cascade. All the drugs in the medicine is proved to have anti-inflammatory, anti-oxidant and anti- arthritic actions.[21,22,23,24] This helps in cessation of inflammatory cascade , prevents formation of free radicles and further destruction of joints. *A. sativa* is proved to have immunomodulatory, anti-oxidant actions which might have shown efficacy in Rheumatoid arthritis

which is an auto-immune condition.[25] By the virtue of all the above properties and proven actions of drugs, PS might have shown effective results in management of RA. Due to the reduction in severity of signs and symptoms, functional capacity and quality of life of patients also improved effectively. Though both trial and control medicine of this study have similar properties and actions, PS is stronger in terms of potency and other functions compared to SNG. PS is having self-generated alcohol which attributes to the added efficacy and helps in faster action with better absorption. Due to above said actions, Group B (PS) might have shown better results than group A (SNG) in management of Rheumatoid arthritis. The overall assessment shows that in group A maximum number of patients had slight improvement whereas in group B maximum number of patients had moderate and marked improvement. No patients had complete remission of signs and symptoms in both the groups. All symptoms effectively reduced on 15th day and after treatment (30th day) of assessment. But it was observed that there was increased in severity of all the parameters in few patients on follow up in both the groups. This might be due to chronicity of the disease, small sample size and short study duration. Hence for better assessment of the trail drug, the medicine have to be administered for longer duration in large sample size. (Figure 1)

CONCLUSION

In the present study two different formulations were selected, SNG for the control group and PS for the trial group. The efficacy of these formulations were evaluated individually in the management of Rheumatoid Arthritis and was found to be statistically significant. On comparison *Prasarini sandhanam* showed better results than *Simhanada guggulu*.

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ORCID

Ramyashree Nagendra, https://orcid.org/0000-0002-1406-4481

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Table 1: Intervention

S. no	Group	Group	Medication	Dose	Anupana	Days
1	Group A	Control group	*Simhanada Guggulu*	2TID (after food)	Warm water	30 days
2	Group B	Trial Group	*Prasarini Sanshanam*	15ml TID (after food)	Warm water	30 days

Table 2: Quantity of drugs Gradings for Pain in the joints: It was assessed using VAS scale. Gradings were used for assessment as follows:

Dravya	Quantity
Gandha Prasarini (Paederia foetida Linn.)	15 kgs (5 adaka)
Jala	60 Liters (4 parts)
Lashuna (*Allium sativum* Linn.)	2 kgs (40 pala)
Guda	2 kgs (40 pala)
Panchakola Churna	1 kg (20 pala)

Table3 : Gradings for pain in the joints

Grade	Nature of pain
Grade 0	No pain (0)
Grade 1	Mild (1 to 3)
Grade 2	Moderate (4 to 6)
Grade 3	Severe (7 to 10)

Table 4: Gradings for stiffness in the joints

Grade	Stiffness
Grade 0	No stiffness
Grade 1	Stiffness lasting for 1-2 hours
Grade 2	Stiffness lasting for 2-8 hours
Grade 3	Stiffness lasting for more than 8 hours

Table 5: Gradings for swelling in the joints

Grade	Swelling
Grade 0	No swelling
Grade 1	Swelling in 1-2 major joints
Grade 2	Swelling in 3-5 major and minor joints
Grade 3	Severe swelling in all major and minor joints

Table 6 : Gradings for tenderness in the joints

Grade	**Tenderness**
Grade 0	No tenderness
Grade 1	Subjective experience of tenderness
Grade 2	Wincing of face on exerting pressure
Grade 3	Wincing of face with withdrawal of affected parts on exerting pressure
Grade 4	Resists touching

Table 7 : Gradings for warmth in the joints

Grade	**Warmth**
Grade 0	Normal Temperature
Grade 1	Raised temperature in 1-3 major and minor joints
Grade 2	Raised temperature in 4-6 major and minor joints
Grade 3	Raised temperature in all major and minor joints

Table 8 : Gradings for *Samanya lakshanas* of *Amavata*

Grade	***Samanya lakshanas (General signs and symptoms)***
Grade 0	No *lakshans*
Grade 1	0-5 *lakshanas*
Grade 2	*Lakshanas* between 5-10
Grade 3	More than 10 *lakshanas* elicited

Table 9 : Gradings general functional capacity

GRADE	**GENERAL FUNCTIONAL CAPACITY**
GRADE 0	Complete ability to carry on all routine activities
GRADE 1	Adequate normal daily activity despite slight difficulty in joint movements
GRADE 2	Few activities but patient can take care of himself
GRADE 3	Few activities and patient requires support from an attender
GRADE 4	Patient is totally bedridden

Table 10 : Degree of disease activity score

GRADE	0	1	2	3
Fatigue	Not there	Works full time despite fatigue	Patient must interrupt work to rest	Fatigue at rest
Grip strength	200 mm hg or more	199-200mmhg	119-70mmhg	Under 70 mm Hg
ESR (in 1st hour)	0-20	21-35	36-50	Above 50
Hb(gm%)	12.5 or more	12.4-11	10.9-9.5	<9.5
General Function	All activities without difficulty	Most of the activities but with difficulty	Few activities, cares for self	Little self-care mainly on wheel chair
Patents estimate	Fine	Almost well	Pretty good	Pretty bad
Physicians estimate	Severely active	Moderately	Minimally	Inactive
Foot pressure	21-25 kg	16-20kg	15-10kg	<10kg
Walking time for 30feet	15-20s	21-30s	31-40s	>40s

Table 11 : Pain in the joints between Group A and Group B

Pain in the joints between Group A and Group B						
Group	Time - period	N	Mean rank	Sum of ranks	P Value	Significance
A	After Treatment	15	20.70	310.50	0.01	S
B		15	10.30	154.50		
A	After Follow up	15	20.17	302.50	0.003	HS
B		15	10.83	162.50		

Table 12 : Swelling in the joints between Group A and Group B

Swelling in the joints between Group A and Group B						
Group	Time - period	N	Mean rank	Sum of ranks	P Value	Significance
A	After Treatment	15	20.07	301.00	<0.001	HS
B		15	9.57	134.00		
A	After Follow up	15	18.80	282.00	0.008	HS
B		15	10.93	153.00		

Table 13: Stiffness in the joints between Group A and Group B

Stiffness in the joints between Group A and Group B						
Group	Time - period	N	Mean rank	Sum of ranks	P Value	Significance
A	After Treatment	15	21.00	315.00	<0.001	HS
B		15	10.00	150.00		
A	After Follow up	15	20.53	308.00	0.001	HS
B		15	10.47	157.00		

Table 14 : Tenderness in the joints between Group A and Group B

Tenderness in the joints between Group A and Group B						
Group	Time – period	N	Mean rank	Sum of ranks	P Value	Significance
A	After Treatment	15	21.33	320.00	<0.001	HS
B		15	9.67	145.00		
A	After Follow up	15	20.73	311.00	<0.001	HS
B		15	10.27	154.00		

Table 15: Warmth in the joints between Group A and Group B

Warmth in the joints between Group A and Group B						
Group	Time - period	N	Mean rank	Sum of ranks	P Value	Significance
A	After Treatment	15	20.97	314.50	<0.001	HS
B		15	10.03	150.50		
A	After Follow up	15	20.73	311.00	<0.001	HS
B		15	10.27	154.00		

Table 16: Barthel's index score between Group A and Group B

Barthel's index score between Group A and Group B						
Group	Time - period	N	Mean rank	Sum of ranks	P Value	Significance
A	After Treatment	15	9.57	143.50	<0.001	HS
B		15	21.43	321.50		
A	After Follow up	15	9.47	142.00	<0.001	HS
B		15	21.53	323.00		

Table 17: General Functional Capacity between Group A and Group B

General Functional Capacity between Group A and Group B						
Group	Time - period	N	Mean rank	Sum of ranks	P Value	Significance
A	After Treatment	15	19.80	297.00	0.005	HS
B		15	11.20	168.00		
A	After Follow up	15	19.10	286.50	0.017	HS
B		15	11.90	178.50		

Table 18 : Samanya Lakshanas between Group A and Group B

Samanya Lakshanas between Group A and Group B						
Group	Time - period	N	Mean rank	Sum of ranks	P Value	Significance
A	After Treatment	15	21.00	315.00	< 0.001	HS
B		15	10.00	150.00		
A	After Follow up	15	20.80	312.00	<0.001	HS
B		15	10.20	153.00		

Table 19 : Degree of Disease Activity Score between Group A and Group B

Degree of Disease Activity Score between Group A and Group B							
Group	Time - period	N	Mean	S.D	S.E	P Value	Significance
A	After Treatment	15	15.47	4.565	1.179	< 0.001	HS
B		15	6.20	2.808	0.752		
A	After Follow up	15	15.13	5.566	1.437	< 0.001	HS
B		15	6.33	5.260	1.358		

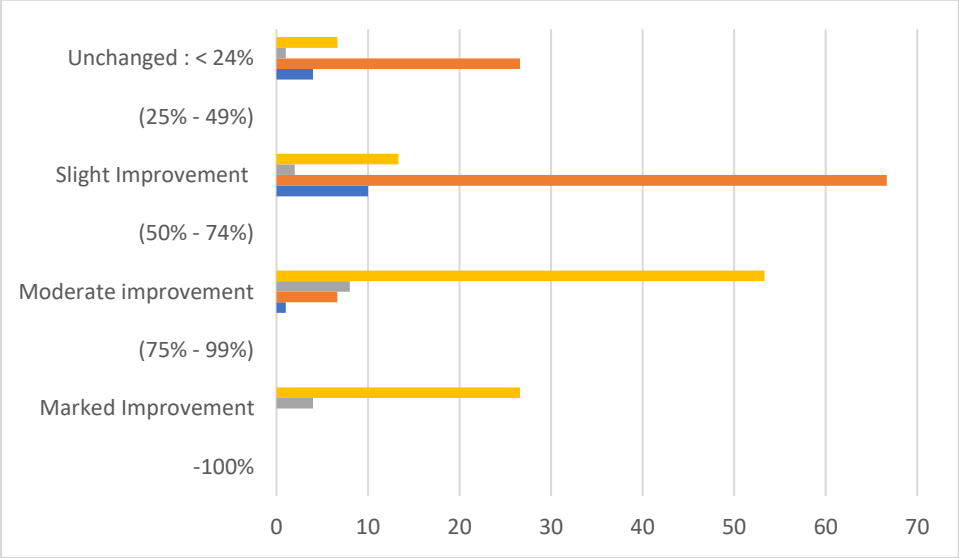


Figure 1: Overall assessment

Flow Chart 1 : Outflow of the patients in the study.

LOCF: Last Observation carried forward

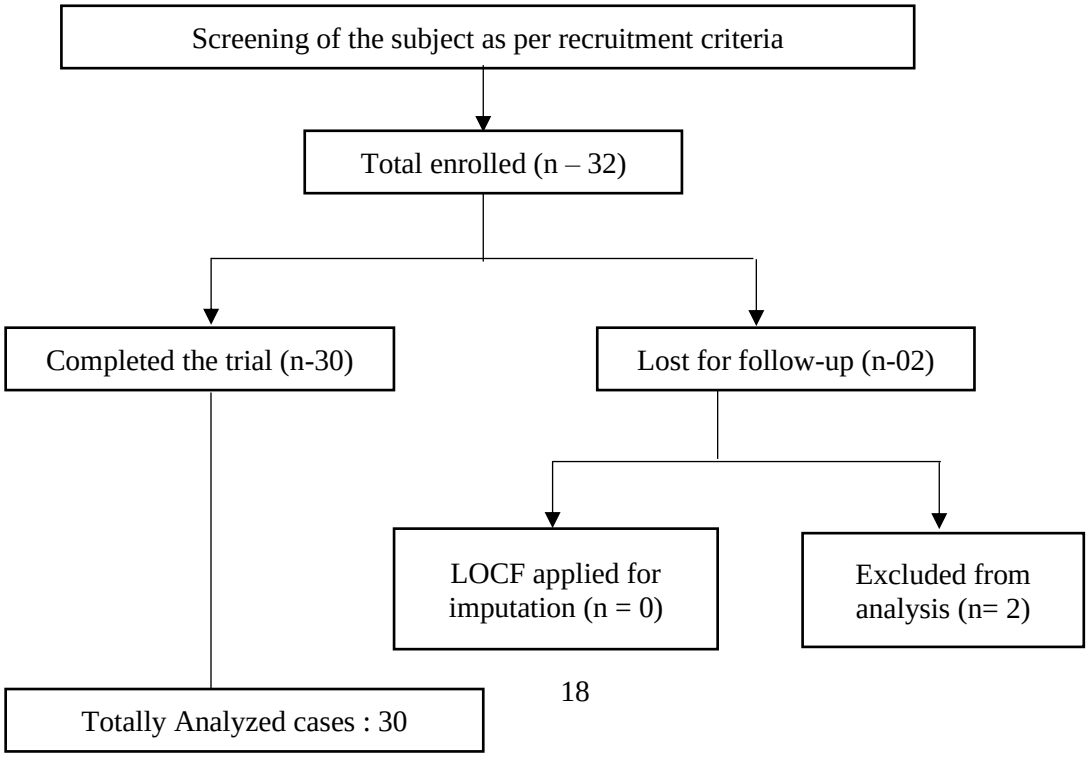
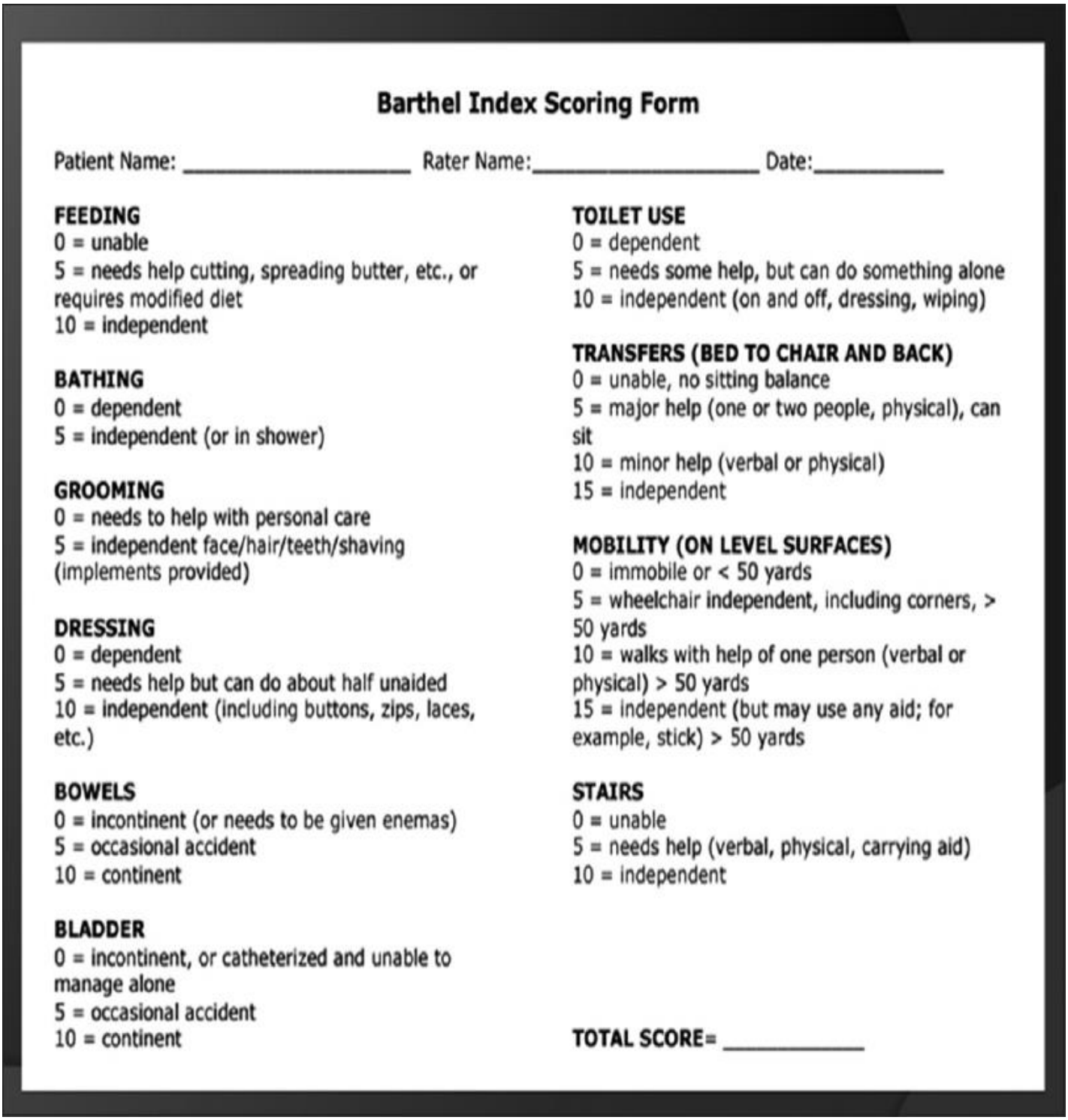


Figure 2: Barthel's index score



Barthel Index Scoring Form

Patient Name: _____ Rater Name:_____ Date:_____

FEEDING
0 = unable
5 = needs help cutting, spreading butter, etc., or requires modified diet
10 = independent

BATHING
0 = dependent
5 = independent (or in shower)

GROOMING
0 = needs to help with personal care
5 = independent face/hair/teeth/shaving (implements provided)

DRESSING
0 = dependent
5 = needs help but can do about half unaided
10 = independent (including buttons, zips, laces, etc.)

BOWELS
0 = incontinent (or needs to be given enemas)
5 = occasional accident
10 = continent

BLADDER
0 = incontinent, or catheterized and unable to manage alone
5 = occasional accident
10 = continent

TOILET USE
0 = dependent
5 = needs some help, but can do something alone
10 = independent (on and off, dressing, wiping)

TRANSFERS (BED TO CHAIR AND BACK)
0 = unable, no sitting balance
5 = major help (one or two people, physical), can sit
10 = minor help (verbal or physical)
15 = independent

MOBILITY (ON LEVEL SURFACES)
0 = immobile or < 50 yards
5 = wheelchair independent, including corners, > 50 yards
10 = walks with help of one person (verbal or physical) > 50 yards
15 = independent (but may use any aid; for example, stick) > 50 yards

STAIRS
0 = unable
5 = needs help (verbal, physical, carrying aid)
10 = independent

TOTAL SCORE= _____