

Comparison of Safety and Efficacy of Sulfasalazine and Pain Killers (Aceclofenac) In Lower Backpain Condition

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ABSTRACT:

Aim: The aim of the study was to compare the safety and efficacy of sulfasalazine and painkillers(aceclofenac) in lower backpain condition.

Materials and methods:A prospective, observational study was conducted on 100 patients suffering with lower backpain condition in Durgabai Deshmukh hospital, Vidyanagar. Of these 50 patients were treated with sulfasalazine (200 mg once day) and other 50 were treated with aceclofenac (100 mg twice daily).The main end aim was the baseline change in the Visual Analog Scale (VAS) at 6 weeks after treatment with medicines and safety profiles.

Results: Significant VAS decrease was seen for both sulfasalazine and aceclofenac in post treatment groups. Sulfasalazine patients demonstrated substantial increase in heartburn and indigestion as compared to aceclofenac. Out of 50 patients prescribed by sulfasalazine only 36 have reduced the pain and remaining 14 have prescribed with aceclofenac, which shown the significant reduction in pain.

Conclusion: aceclofenac was proven to be more effective in lower backpain condition when compared to sulfasalazine, without any major side effects.

Keywords: Aceclofenac, Sulfasalazine, Lower back chronic discomfort, NSAIDs.

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I. INTRODUCTION:

- Pain is an unpleasant sensory and emotional experience associated with potential tissue damage. Chronic pain is any pain that lasts for more than 3 months. It may arise from initial injury, or may be of ongoing cause, or other health problems.

- Low back pain is considered to be chronic if it is present more than 3 months. The pain may be of bone pain, nerve pain, or muscle pain. Pain is measured by the visual analogue scale.

- 'Lower back pain' is a common painful condition affecting the lower portion of the spine. Back pain can range from a muscle aching to a shooting, burning or stabbing sensation.

Causes:

- Back pain often develop without a cause which can be identified using imaging study.

Conditions linked to back pain include:

1. Muscle or ligament strain: Repeated heavy lifting can strain back muscles and spinal ligaments.
2. Bulging ruptured disks: Nucleus of Intervertebral disc gets bulges or ruptured and press on nerve.
3. Arthritis: Osteoarthritis affects lower back.
4. Spinal stenosis: Narrowing of space around spinal cord.
5. osteoporosis: spines vertebrae develop painful fractures when bones becomes porous and brittle.

Risk factors:

- Age: lower back pain can start at the age of 30-40. Lack of exercise unused muscle in lower back can cause back pain.
- Excess weight.

Disease: some types of arthritis and cancer also contribute to pain in lower back area.

Improper lifting: using back instead of legs during lifting.

Psychological conditions: Depression and anxiety can increase risk of pain. Smoking promotes coughing and can lead to herniated disks and also decreases blood flow to the spine and increases risk of osteoporosis.

Prevention: Lower back pain can be treated by improving physical condition by:

- Exercises
- Build muscle strength and flexibility
- By maintaining healthy weight.
- Quit smoking.
- Avoid strain on your back.

II. MATERIAL AND METHODS:

For this study, consent of Institutional ethics committee, Durgabhai Deshmukh hospital was taken. This prospective observational study was conducted for 6 months in department of orthopedics, Durgabhai Deshmukh hospital, a 300 bedded multispeciality hospital.

A study was conducted to evaluate patients with lower back pain. Baseline demographic data was collected from the patient case reports. Patients of age group 20-80 years are taken into the study. Patients less than 20 years and more than 80 years are excluded.

III. RESULTS AND DISCUSSION:

In the current clinical study, we have conducted a prospective observational study for 6 months on 100 subjects suffering with lower backpain condition in Durgabai Deshmukh hospital, Vidyanagar. Of these 50 subjects were treated with sulfasalazine (200 mg once day) and other 50 were treated with aceclofenac (100 mg twice daily). The main end aim was the baseline change in the Visual Analog Scale (VAS) at 6 weeks after treatment with medicines and safety profiles. Regular observation of each patient was observed and results have been interpreted. The recorded data of each patient was entered into our data collection form which is designed to meet our study requirements. Results have been displayed below based on our objective of study using bar diagrams and pie diagrams.

TABLE: 1 AGE GROUP.

AGE IN YEARS	FREQUENCY	PERCENTAGE%
35-40	5	5%
40-45	9	9%
45-50	12	12%
50-55	16	16%
55-60	18	18%
60-65	20	20%
65-70	20	20%

Inpatients with chronic lower back pain when compared to others, age group between 60-65(20%) and 65-70(20%) are more prone to lower back pain.

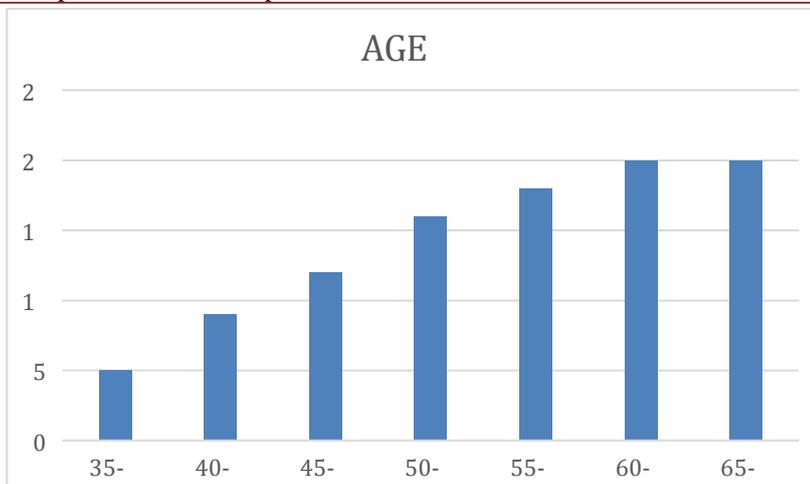


Figure 1: Comparison of age groups.

Result: in patients with lower back pain when compared to others, age group between 60-65(20%) and 65-70 (20%) are more prone to lower back pain.

TABLE:2 GENDER.

GENDER	FREQUENCY	PERCENTAGE
MALE	24	26%
FEMALE	76	76%

Outof100patientswithlowerbackpain, Malepatientswere24(24%)andfemalepatientswere76(76%).

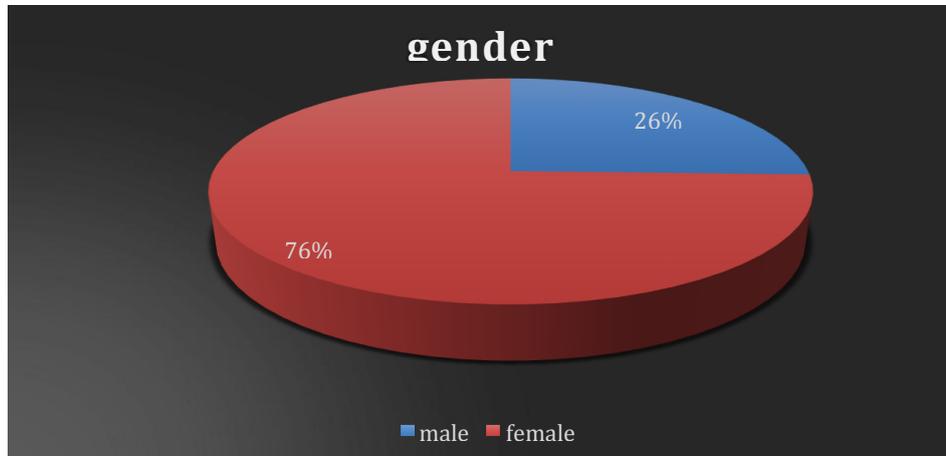


Figure 2: Gender of the patient.

Result: Out of 100 patients with lower back pain, male subjects were 26(26%) and female subjects were 76(76%).

TABLE: 3 COMORBIDITIES.

CO-MORBIDITIES	FREQUENCY	PERCENTAGE%
Inflammatoryboweldisease	10	25
Osteoporosis	17	42
Smoking	13	33

Out of 60patientswithlower back pain, patientwithriskfactorcomorbiditiesareinflammatorybowel disease(25%), osteoporosis(42%), smoking(33%).

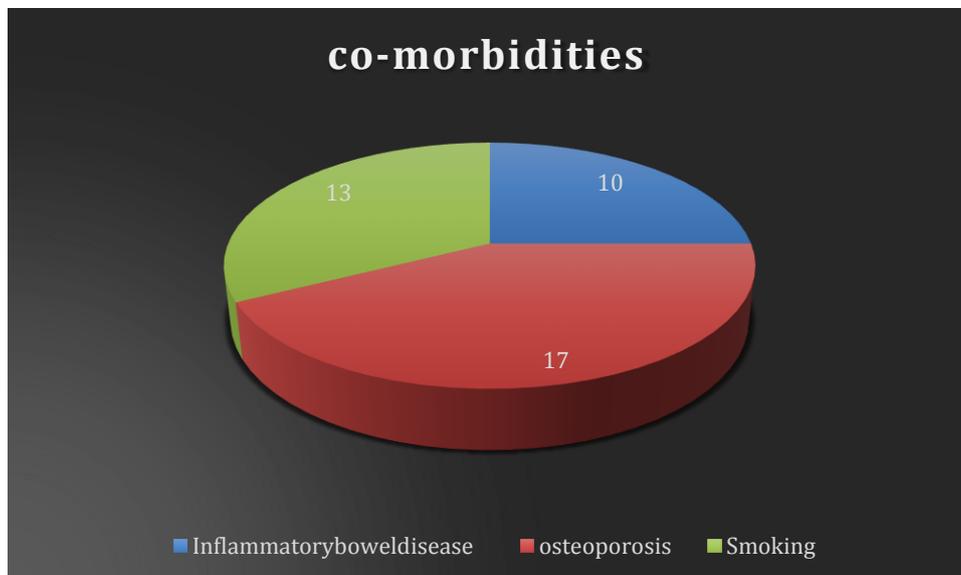


FIGURE: 3 Comorbidities

TABLE: 4 EFFICACY OF SULFASALAZINE:

	REVIEWS	Visual Analogue Scale	FREQUENCY
EFFICACY OF SULFASALAZINE	review 1	Mild	0
		Moderate	50
		Severe	0
	Review 2	Mild	11
		Moderate	5
		Severe	0
	Review 3	Mild	5
		Moderate	7
		Severe	0
	Review 4	Mild	0
		Moderate	0
		Severe	0

Result: Out of 50 patients prescribed by sulfasalazine only 36 have reduced the pain and remaining 14 have prescribed with aceclofenac.

Review 1: 50 members were complaining with moderate pain.

Review 2: 11 patients relieved from pain.
5 patients with moderate pain.

Review 3: 5 patients relieved from pain.
7 patients with moderate pain.

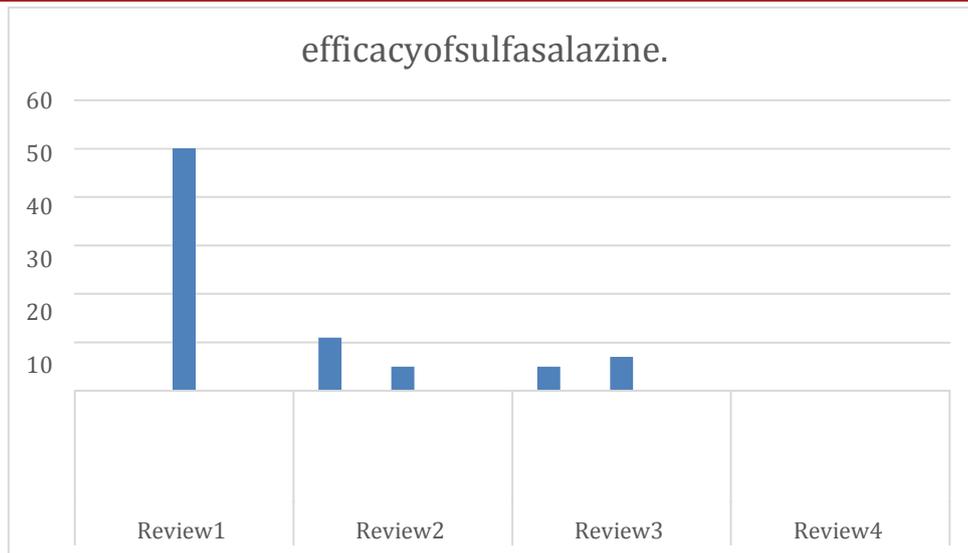


Figure 4: efficacy of sulfasalazine.

TABLE 5: EFFICACY OF ACECLOFENAC.

	REVIEWS	Visual Analogue Scale	FREQUENCY
EFFICACY OF ACECLOFENAC	review 1	Mild	0
		Moderate	50
		Severe	0
	Review 2	Mild	23
		Moderate	24
		Severe	0

	Review 3	Mild	18
		Moderate	5
		Severe	0
	Review 4	Mild	10
		Moderate	1
		Severe	0

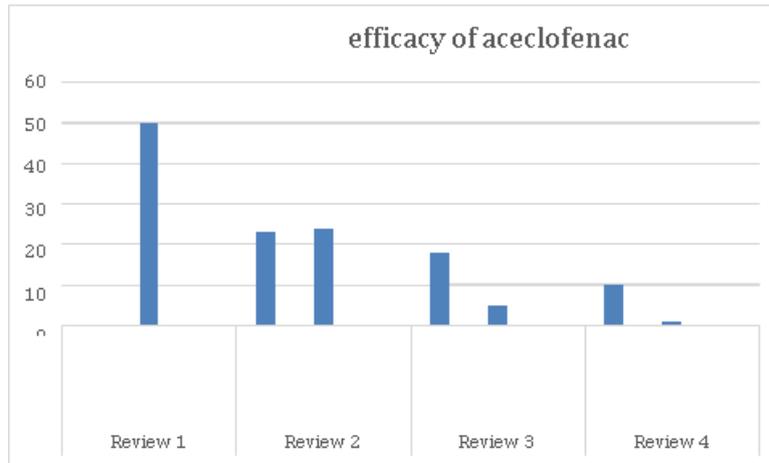


Figure 4: Efficacy of aceclofenac.

Review 1: 50 patients were complaining with moderate pain.

Review 2: 23 patients were relieved from pain.

24 patients with moderate pain.

Review 3: 18 patients relieved from pain.

5 patients were with moderate pain.

Review 4: 10 patients relieved from pain.

1 patient with moderate pain.

Table 6. Assessment of Gastrointestinal effects.

Gastrointestinal symptom	Sulfasalazine (n=47)	Aceclofenac (n=50)	p value
Nausea, n (%)	2 (4.3)	1 (2.0)	0.61
Indigestion, n (%)	4 (8.5)	1 (2.0)	0.195
Heartburn, n (%)	10 (21.3)	3 (6.0)	0.037
Diarrhea, n (%)	1 (2.1)	0 (0.0)	0.485

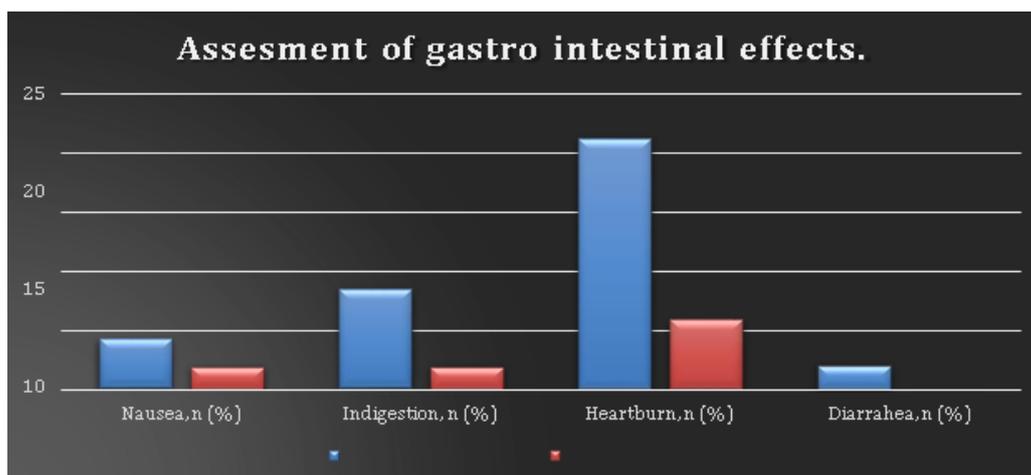


Figure 5: Assesment of gastrointestinal effects.

Result: compared with aceclofenac side effects of sulfasalazine are more. Among the side effects sulfasalazine have shown major side effect of heart burn. Due to this major side effect aceclofenac was prescribed to remaining patients.

STATISTICAL TOOL:

All attributes have been summarized descriptively. Numbers and percentages were utilized for categorical data in the data summaries. Data analysis using chi-square. For easy comprehension, the findings were represented using tables and graphs.

COMORBIDITIES:

H₀: Co-morbidities are related to gender.

H₁: Co- morbidities are not related to gender.

Observed frequency(O _i)	Expected frequency(E _i)	(O _i -E _i)	(O _i -E _i)/E _i
5	4.5	0.25	0.05
6	8.07	4.14	0.51
8	6.17	3.66	0.59
5	5.25	0.5	0.09
11	8.9	4.2	0.47
5	6.8	3.6	0.52
Total			2.23

Degree of freedom: (r-1)*(c-1)

No.of rows(r)	No. of columns (c)	Degree of freedom (f)
2	3	2

As degree of freedom is 2, chi-square table value is 5.99.

The calculated table value is 2.23 which is less than chi-square table value, null hypothesis (H₀) is accepted.

As the values of the side effects of sulfasalazine and aceclofenac are very small we can't consider z-test and chi-square test.

IV. Conclusion:

In patients with above condition, the study showed that aceclofenac is more effective than sulfasalazine with low side effects, with respect to pain relief using visual analogue scale(VAS).

Sulfasalazine has slightly increased gastrointestinal effects compared to the aceclofenac, such as indigestion and heart burn.

Aceclofenac have improved the condition without any major side effects and is the best prescribed for the lower back pain when compared to sulfasalazine.

ETHICS AND CONSENT:

The entire study was conducted according to the AHA/ASA guidelines. All the relevant and necessary data was collected from inpatient records, laboratory reports, prescriptions and by interviewing the patients.

CONFLICTS OF INTREST:

None.

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