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Original Research Article

Assessing the Impact of Serratiopeptidase and Diclofenac Sodium on Post-Operative Pain and Inflammation in Day Care Gynecological and Obstetric Procedures

Neha Kumari[1], Sadhana Singh[2], Kamlesh Tiwary[3]

[1]Assistant professor, Department of Obstetrics and Gynaecology, RDJM Medical College and Hospital, Turki, Muzaffarpur, Bihar, India

[2]Professor and HOD, Department of Obstetrics and Gynaecology, RDJM Medical College and Hospital, Turki, Muzaffarpur, Bihar, India

[3]Professor, Department of Obstetrics and Gynaecology, RDJM Medical College and Hospital, Turki, Muzaffarpur, Bihar, India

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Corresponding Author: Dr. Neha Kumari
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Abstract

Background: Postoperative pain substantially impacts of patients' quality of life and functional recovery. Higher-than-expected pain levels after some surgeries were identified by Gerbershagen et al., mostly in obstetrics and gynecology. Effective postoperative pain management is crucial, often involving a multimodal approach to reduce acute pain and prevent its transition to chronic pain.

Aim: The purpose of this study was to evaluate the efficacy of a fixed-dose combination of 100 milligrams of diclofenac sodium and 10 milligrams of serratiopeptidase for the treatment of pain during various obstetric and gynecological procedures.

Methodology: This prospective study enrolled 70 patients in two groups, each group consisted of 35 patients. Group 1 received Serratiopeptidase, while Group 2 received Aceclofenac. Pain intensity was assessed using the visual analogue scale, and limb swelling was measured at baseline, one week, and two weeks post-treatment. Statistical analysis was performed using SPSS software.

Results: Both groups demonstrated reductions in swelling and improvements in VAS scores over time. Group 1's average swelling decreased from 270.45 ml to 258.30 ml, while Group 2's decreased from 319.85 ml to 307.10 ml, with no significant differences between groups (p-values > 0.05). However, Group 2 exhibited significantly lower VAS scores in smaller limb volume categories at both one and two weeks (p-values ≤ 0.0001).

Conclusion: Although both treatments led to improvements in swelling and pain management, Group 2 showed superior efficacy in smaller limb volumes. The findings suggest that more research was required to maximize treatment approaches for managing pain following surgery, particularly with regard to limb volume changes.

Keywords: Diclofenac Sodium, Gynecology, Postoperative Pain, Serratiopeptidase, Visual Analogue Scale

Introduction

Pain after surgery is a serious side effect that can reduce patients' overall quality of life and hinder their ability to recover properly. Gerbershagen et al. discovered that postoperative pain levels were higher than expected after a variety of common mild to moderate surgical procedures, including multiple laparoscopic operations [1]. This study found that patients in obstetrics and gynecology had higher pain scores than those in other surgical departments. Inflammation plays a crucial part in the pathophysiology of postoperative pain. Surgical procedures cause tissue injury and the formation of inflammatory cells at the surgical site, both of which create inflammatory mediators that eventually lead to tissue inflammation [2]. Treatments with anesthetics or analgesics were used to stop postoperative pain from potentially becoming chronic. These treatments reduce the incidence and intensity of acute discomfort during and soon after surgery [3]. Modern methods of managing pain after surgery include the use of peripheral nerve blocks, systemic non-opioid and opioid analgesics, and other pharmaceutical drugs to reduce pain as needed [4].

Surgeons had focused on enhancing aspects of patient care in response to the contemporary focus

on managed care and reduced hospitalizations. Minimizing or completely alleviating post-operative discomfort, without undue sedation, facilitates swift mobilization and restoration of autonomy. Postoperative ileus and other negative analgesic side effects may be reduced with targeted multimodal pain management [5]. A proteolytic substance called serratiopeptidase is used to reduce inflammation. Because of this enzyme's anti-edema and anti-inflammatory qualities, enteric coated oral formulations are often used in gynecology, surgery, orthopaedics, otolaryngology, and dentistry, among other medical specialties [6].

Nonsteroidal anti-inflammatory medicines had shown their efficacy as analgesics when used in conjunction with surgery, as shown by decreases in pain scores or a sparing impact on opioids [7]. One Nonsteroidal anti-inflammatory drugs that was commonly used for pain relief is diclofenac. There is a lack of information about the therapeutic efficacy of serratiopeptidase and diclofenac sodium for symptom relief, especially in obstetric and gynecological operations, despite their safety and effectiveness [8]. The aim of this study was to treat post-operative pain and inflammation in day care obstetric and gynecological operations using serratiopeptidase and diclofenac sodium.

Methodology

Study Design

This prospective study was conducted over a period of one year in the Department of Obstetrics and Gynecology at RDJM Medical College and Hospital, Turki, Muzaffarpur, Bihar, India . The objective of the study was to evaluate the use of the paperless partogram as a bedside tool for labor management

Sample Size and Sample Collection

A total of 70 patients aged 15-60 years were recruited, randomized into two groups of 35 each. Randomization was carried out using a computer-generated schedule (Microsoft Excel). Group 1 received serratiopeptidase 10 mg three times a day for two weeks, while Group 2 received Aceclofenac 100 mg twice a day for the same duration.

Inclusion and Exclusion Criteria

Inclusion Criteria: Patients with soft tissue injuries such as ligament sprains, synovitis, muscle strains, contusions, tenosynovitis, post-traumatic bursitis, and periarthritis due to falls or trauma were included.

Exclusion Criteria: Patients with fractures, infected wounds, multiple injuries, requiring surgery under general and spinal anesthesia, or having systemic disorders (respiratory conditions, renal, or cardiovascular). pregnancy, lactation, hyperacidity, peptic ulcers, bleeding disorders, also a history of allergy to nonsteroidal anti-inflammatory drugs were excluded from the study.

Procedure:

Upon enrollment, baseline limb circumferences of the normal and injured limbs were measured using a Gulick tape on Day 0. Limb volumes were calculated using a truncated cone model equation and classified into five categories based on swelling volume: less than 200 ml, 200-400 ml, 400-600 ml, 600-800 ml, and more than 800 ml. Limb circumference was measured on follow-up visits during Week 1 and Week 2. Pain intensity was assessed using a ten centimeters visual analogue scale at the same time points. All measurements were performed by the same investigator to ensure consistency.

Statistical Analysis:

The statistical analysis was conducted using SPSS software, specifically version 27. The results were interpreted to assess the effectiveness of the partogram in managing labor. Either the Chi-square test was used to analyze categorical data. The P-value below 0.05 was indicated the statistical significance of result.

Result

Table 1 compared the swelling measured in milliliters before and after the first week of treatment for the individuals in Groups 1 and 2. Group 1's average edema before treatment was 270.45 ± 192.10 ml, whereas Group 2's average swelling was 319.85 ± 198.50 ml. Following a week of therapy, the swelling in Group 1 dropped to 258.30 ± 180.00 ml, while the swelling in Group 2 dropped to 307.10 ± 193.75 ml, with a p-value of 0.115. Group 1 experienced an arithmetic difference in swelling of -12.15 ± 6.25 ml, while Group 2 experienced -12.75 ± 5.80 ml. For Group 1, the percentage decrease in swelling was 4.5% ± 3.0%, while for Group 2, it was 4.0% ± 2.2%.

Table 1: swelling assessments at the first week and before to treatment in Groups 1 and 2

Study Groups	Group 1	Group 2	p-value (MW)
Before Treatment	270.45 ± 192.10	319.85 ± 198.50	0.135
1st Week Treatment	258.30 ± 180.00	307.10 ± 193.75	0.115
Arithmetic Difference	-(12.15 ± 6.25)	-(12.75 ± 5.80)	
Percentage Difference	-(4.5 ± 3.0)	-(4.0 ± 2.2)	

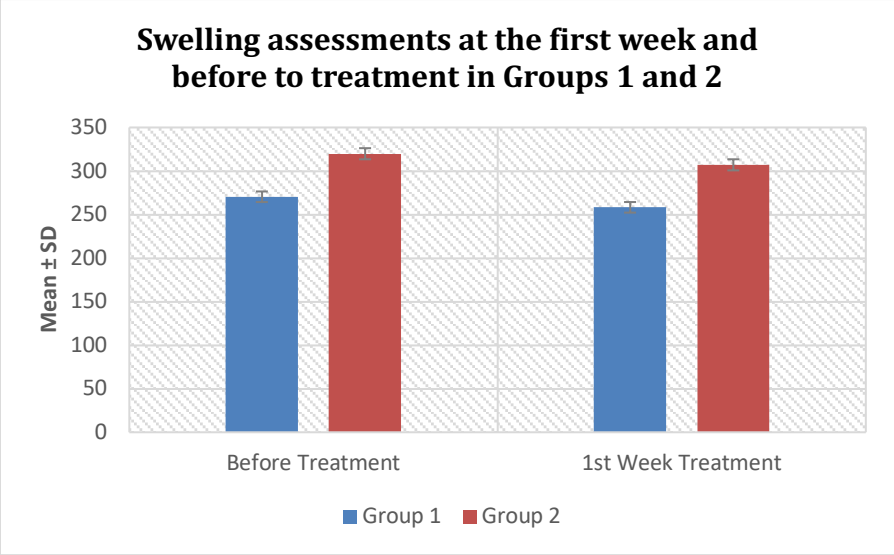

Figure 1: swelling assessments at the first week and before to treatment in Groups 1 and 2.

Table 2 shows the patients' swelling assessments at the second week of therapy as compared to their pre-treatment assessments for each of the two groups. Group 1 experienced a mean decrease in edema of 14.67 ± 8.20 ml (about 6.2%), going from an average of 235.12 ± 170.48 ml prior to treatment to 220.45 ± 160.35 ml in the second week. Comparably, Group 2 showed a decline with a mean of 15.13 ± 7.80 ml (approximately 5.3%), going from 300.90 ± 183.12 ml to 285.77 ± 174.21 ml. The p-values for both assessments (0.145 for the second week and 0.135 before to treatment) showed no statistically significant differences in the two groups' reduction of swelling.

Table 2: swelling assessments both before and during the second week of therapy in Groups 1 and 2.

Study Groups	Group 1	Group 2	p-value (MW)
2nd Week Treatment	220.45 ± 160.35	285.77 ± 174.21	0.145
Before Treatment	235.12 ± 170.48	300.90 ± 183.12	0.135
Arithmetic Difference	-(14.67 ± 8.20)	-(15.13 ± 7.80)	
Percentage Difference	-(6.2 ± 4.1)	-(5.3 ± 3.7)	

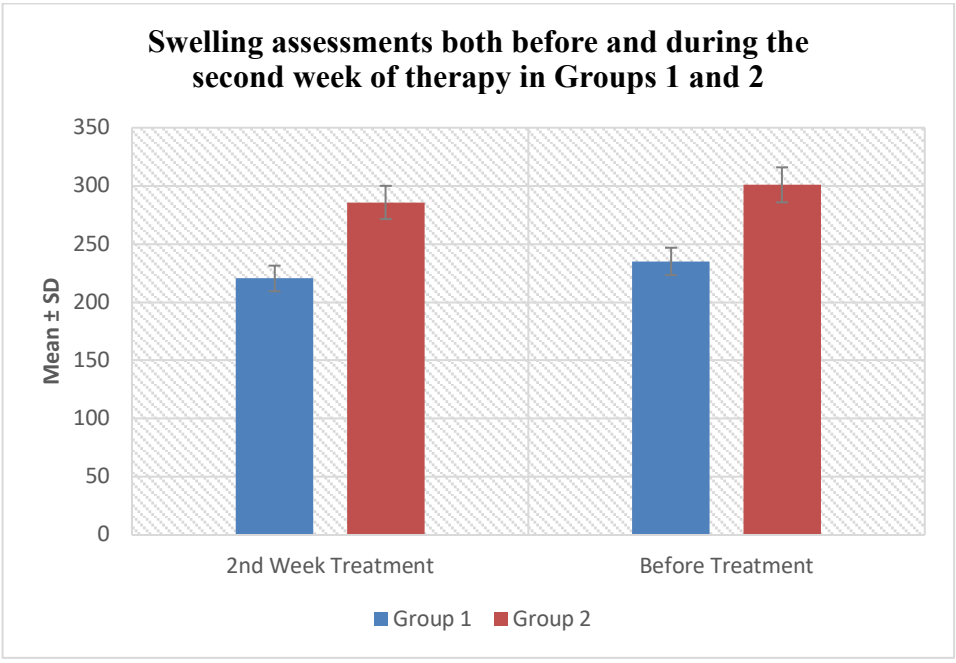

Figure 2: swelling assessments both before and during the second week of therapy in Groups 1 and 2.

Table 3 displays the average visual analog scale scores for the two groups (Group 1 and Group 2) obtained prior to therapy, at the first week, and at the second week, for various limb volume categories '(less than 200 ml, 200–400 ml, 400–600 ml, and 600–800 ml).' In the "less than 200 ml" category, Group 2 significantly outperformed Group 1 at both the first and second weeks (p-values ≤ 0.0001), with both groups demonstrating steady improvements with time. Similar to this, Group 2 showed considerably lower scores in the "200–400 ml" category in the first and second weeks (p-values ≤ 0.0001), while the pre-treatment scores were similar (p-value = 0.856). While there was a gradual improvement in the "400–600 ml" category, the differences were not statistically in the first week (p = 0.52) but were in the second week (p = 0.0001). Finally, no significant variation were seen at any time point for the "600–800 ml" group (p-values ranged from 0.267 to 0.533). Overall, the findings reveal that with time, VAS scores decreased for both groups, with Group 2 exhibiting a more noticeable effect in the smaller limb volume categories.

Table 3: First week, second week, and pre-treatment average VAS scores for Groups 1 and 2.

Limb Volume (milliliters)	Before	1st Week	2nd Week
Less Than 200 milliliters			
Group 1	5.73	2.81	1.55
Group 2	5.31	0.95	0.09
p-value (MW)	0.457	0.0001	0.0001
200 – 400 milliliters			
Group 1	5.61	2.36	1.62
Group 2	4.5	0.3	0
p-value (MW)	0.857	0.0001	0.0001
400 – 600 milliliters			
Group 1	6.74	4.5	2.25
Group 2	6.65	3.07	0.36
p-value (MW)	0.945	0.52	0.0001
600 – 800 milliliters			
Group 1	7	4.5	1.5
Group 2	6.76	3	0.5
p-value (MW)	0.8	0.268	0.534

Discussion

This study indicated that both Group 1 and Group 2 experienced reductions in swelling and improvements in Visual Analog Scale (VAS) scores over the treatment period; on the other hand, there were no statistically significant variations in edema decrease among the two groups. Before treatment, Group 1 had an average swelling of 270.45 ml, while Group 2 had a slightly higher average of 319.85 ml. Following one week of therapy, both groups demonstrated similar decreases in swelling, with Group 1 reducing to 258.30 ml and Group 2 to 307.10 ml, reflected by p-values of 0.135 also 0.115, respectively, indicating no significant difference between the groups. By the second week, both groups continued to show reductions in swelling, with Group 1 decreasing by approximately 6.2% and Group 2 by 5.3%, again without significant differences (p = 0.145). Aso et al. [9] reported similar results about serratiopeptidase in 1981 on seventy patients with fibrocystic breast disease, concluding that serratiopeptidase was superior to a placebo for induration, edema, and breast discomfort. Serratiopeptidase's effectiveness as an anti-inflammatory enzyme was further supported by a 1984 test conducted by Tachibana M et al. [10]. A double-blind study by Esch et al. [11] evaluated the effect of "serratiopeptidase on postoperative edema" and pain in 66 individuals receiving therapy for a ruptured knee ligament. Compared to the control group, patients who received "serratiopeptidase" saw a 50% reduction in edema and quicker pain alleviation. In a double-blind study, serratiopeptidase outperformed a placebo in reducing induration, edema, and breast pain [12]. Mazzone A et al. [13] characterized the 'effects of serratiopeptidase as anti-inflammatory, fibrinolytic, anti-oedemic, and analgesic in 1990.'

In terms of VAS scores, Group 2 consistently exhibited better outcomes in the smaller limb volume categories throughout both the first and second weeks of treatment. Notably, in the "less than 200 ml" and "200–400 ml" categories, Group 2 showed significant improvements compared to Group 1, with highly significant p-values (≤ 0.0001). However, the differences in larger limb volume categories (400–600 ml and 600–800 ml) were less pronounced and did not achieve statistical significance, suggesting that the treatment's effectiveness may vary based on limb volume. Our results were consistent with the 2001 study by Dooley M et al. [14], which demonstrated aceclofenac's efficacy as a pain treatment

medication. Another research similarly establish the analgesic efficacy of aceclofenac [15].

These findings indicate the necessity for more study to investigate the underlying mechanisms that contribute to the observed disparities in VAS scores, especially in patients with reduced limb volumes. Additionally, investigating potential factors influencing the effectiveness of the treatments applied in both groups may provide valuable insights into optimizing therapeutic strategies for managing edema and associated pain. Overall, while both groups demonstrated positive outcomes, the distinct differences in VAS scores among smaller limb volumes warrant closer examination to enhance treatment approaches for this patient population. After ambulatory minimally invasive gynecologic surgery, 70% of patients experienced moderate to severe pain, according to electronic patient-reported symptom monitoring [16]. When Diclofenac and Serratiopeptidase were taken together, pain was significantly reduced 24 hours after surgery, both at rest and when moving, as compared to the preoperative period.

Conclusion

Serratiopeptidase had shown promising potential as an effective agent in pain management. Both Groups experienced significant reductions in swelling and improvements in VAS scores over the treatment period, although no statistically significant variation was observed between the two groups. Significantly, Group 2 demonstrated a more pronounced effect in smaller limb volume categories, indicating that treatment efficacy may vary with limb size. The findings underscore the importance of understanding the prevalence of edema in specific populations, which refers to the proportion of individuals affected by swelling within a given group or area. Further research is essential to identify factors that may influence treatment outcomes and to develop tailored therapeutic strategies for managing edema effectively.

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