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EFFECTIVENESS AND TOLERABILITY OF NAPROXEN BETAIN SODIUM (NAPREBEN)

By

**Dr. Syed Asif Ali Shah, M.S.; Professor Syed Muhammad Awais, M.S.
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ABSTRACT:

In this prospective study thirty patients were randomly selected of different age groups from 23 to 80 years having pain due to different musculoskeletal disorders, like low back pain, DJD knees, Cervical Spondylosis, Rheumatoid Arthritis, AVH hip, Plantar fasciatis etc. treated by oral Naproxen Betain Sodium.

Efficacy of the drug was good in 26 patients but 04 patients did not respond the treatment. Three patients develop GIT complaints, six patients had preveious history of acid peptic disease hence their GIT symptoms became worse, overall tolerability was good.

INTRODUCTION

Painful musculoskeletal disorders are the most common presentation in orthopedics out patients department and they are very difficult to treat.

Degenerative joint disease is the most common painful disorder in human beings and the leading cause of disability in the elderly, it has been estimated that 100,000 people in the USA are unable to walk independently from bed to bathroom because of OA. No cure exists for OA. Treatment is aimed at reducing pain, maintaining mobility and minimizing disability.

Drug therapy in OA today is symptomatic, often joint pain can be controlled with only a nonsteriodal anti-inflammatory drug. Naproxen betain sodium is one of the NSAID drugs, it is derived from propionic acid and used world wise. It inhibits the synthesis of prostaglandins in body tissue by inhibiting cyclooxygenase, an enzyme that catalyzes the formation of prostaglandins precursors from arachidonic acid.

AIMS AND OBJECTIVES

To evaluate the effectiveness and tolerability of naproxen Betaine sodium in patients having pain due to musculoskeletal disorders.

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MATERIALS AND METHODS

This prospective study was conducted in the year 2000 at Jinnah Hospital, Lahore affiliated to Allama Iqbal Medical College.

For this purpose, thirty patients were randomly selected having musculoskeletal disorders. Out of thirty patients, twenty one were female, nine were male. Their disease distribution was as follows:

<u>DISEASES</u>	<u>NO. OF PATIENTS</u>
1. DJD Knees	11
2. Low back pain	9
3. Sciatica	1
4. Costochondritis	1
5. Cervical spondylosis	1
6. Frozen Shoulder	1
7. Rheumatoid Arthritis	1
8. AVN Hip	1
9. Dislocation Elbow	1
10. Wrist Sprain	1
11. Plantar Fasciitis	1

Average age was forty-five years (23-80 years)

Oral Naproxen betaine sodium (Napreben) was used. Topical application of the same salt was also tried in patients within DJD Knees, shoulder and elbow pain. Dose of the drug was 550 mg 1 x BD.

All patients were followed up for two weeks for pain, compliance and side effects. Severity of pain was assessed at first visit and after two weeks according to visual analogue scale, which is as follows:

0 25 50 75 100

RESULTS

SEVERITY OF PAIN

Severity of pain at start of treatment was as follows:

Severity of Pain	No. of Patients	%age
Severe pain (100)	07	23.3%
Moderate pain (75)	15	50%
Mild to Moderate (50)	06	20%
Mild (25)	02	6.6%

Severity of pain after two weeks of treatment.

Severity of Pain	No. of Patients	% age
Severe pain (100)	04	13.33%
Moderate pain (75)	03	10%
Mild to Moderate (50)	17	56.6%
Mild (25)	06	20%
No Response to Naproxen	04	13.3%

After two weeks of treatment with oral Naproxen betaine sodium, no patient had severe pain. 13.3% had moderate pain, 10% had mild to moderate pain, 56.6% had mild pain and 100% relief of pain in 20% patients. 13.3% patients did not respond the NSAID drug.

SIDE EFFECTS

GIT disturbance was observed in 09 patients but 06 patients out of 09 were known cases of acid peptic disease. So 03 patients (10%) developed APD. One patient complained of vertigo. Overall compliance was good.

CONCLUSION

It was a very short study, 30 patients were selected and followed for only two weeks but 26 patients (86.6%) responded well, only four patients (13.3%) did not respond the drug in two weeks, three patients (10%) developed acid peptic disease.

The use of Naproxen betaine sodium is justified by its significant therapeutic efficacy and tolerability in painful condition related to musculoskeletal disorders. But we recommend to add H₂-receptor blocker in patients susceptible to acid peptic disease.

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“THE OUTCOME OF POLYTRAMATIZED PATIENTS SUSTAINING BLUNT ABDOMINAL TRAUMA ASSOCIATED WITH PELVIC FRACTURES”

By

Shahzad Alam Shah, FCPS; Syed Asif Ali Shah, MS

ABSTRACT

OBJECTIVES:

To evaluate the outcome of 27 polytraumatized patients sustaining blunt abdominal trauma associated with pelvic ring injury.

STUDY DESIGN:

An observational analytical study.

PLACE AND DURATION OF STUDY:

The study was carried out at The Department of Surgery, Lahore General Hospital, Lahore for a period of 35 months from September 2000 to August 2003.

SUBJECT/METHODS:

Twenty-seven patients sustaining blunt abdominopelvic injury were included. Patients were divided into two groups according to their hemodynamic status at admission. Group A includes patients with persistent hemodynamic instability despite adequate resuscitation and Group B consists of patients with stable hemodynamics despite a relatively high ISS.

RESULTS:

Seventeen patients (62.96%) revealed persistent hemodynamic instability despite adequate resuscitation (group A). Only 10 patients (37.03%) in the study were hemodynamically stable. Patients of Group A exhibited significantly higher ISS (34.2+/-9.6) and lower GCS (10.5+/-5) compared ISS (27.6+/-9.4) and GCS (13.4+/-3.2) of group B patients. Patients with persistent hemodynamic instability (Group A) had a mortality rate of 28.57% (4 out of 14) and Group C patients had 18.18% mortality rate.

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CONCLUSION:

Multiple injured patients with pelvic ring injury needing emergency laparotomy remain a challenge for the general surgeons. The evaluation and treatment of such patients requires a cooperative team approach and a standard approach to these injuries may lead to decreased mortality. A multidisciplinary team involving general surgeons, emergency medicine physicians, and orthopedic surgeons should be involved to ensure the highest standard of care for the injured patient. Patients at risk are those with severe hemodynamic instability and a concomitant head and/or thoracic injury. Unstable pelvic fracture is also a major contributing factor for mortality.

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Introduction

A combination of multiple injuries including blunt trauma abdomen and pelvic ring disruption often represents a devastating injury pattern.^{1,2} About 10% of all pelvic fractures are associated with abdominal visceral injuries and in the group the mortality rate is probably in excess of 20% even in developed countries.³ Associated injuries of other systems like head, chest or musculoskeletal system further aggravate the outcome of these patients. While infection and multiple organ dysfunction syndrome (MODS) are the major complications during the late post traumatic course, exsanguinating haemorrhage represent the predominant lethal factor during the first 24 hours.^{3,4}

In the polytraumatized patients because of multisystem injuries the diagnostic and therapeutic approach is more variable and in the order of emergent treatment is more variable. When multiple organ systems like abdomen, head and chest are involved the treatment algorithm becomes more complex and the reduction and primary fixation of the unstable pelvic fracture is generally not a priority.⁵ Moreover, which are the patients that need urgent stabilization is controversially been discussed in the past.⁶ This article studies the outcome of 27 patients sustaining blunt abdominal trauma with associated pelvic ring injury over a 35 months period. This study identifies the prognostic factors and evaluates the impact of pelvic injuries that were not primarily fixed and stabilized in the ultimate outcome of these patients.

Patients and Method

From September 2000 to August 2003. 27 patients with abdominal trauma including pelvic ring injuries were admitted through the casualty department of Lahore General Hospital Lahore. Patient's Performa was maintained for the mechanism of injury, age, sex, 24 hour transfusion requirement, incidence of shock, SIRS, adult respiratory distress syndrome (ARDS), multiple organ dysfunction syndrome (MODS), and treatment modality. Hemodynamic, respiratory, laboratory, and radiological data were collected until discharge from the hospital. Patient arriving latter than three hours after the incidence and the patients in extremis were not included in this study.

Patients were divided into two groups according to their hemodynamic status at admission: Group A included patients not able to maintain a systolic blood pressure of >90 mmHg, a pulse of <100 beats/minute, a central venous pressure (CVP) >5 cm H₂O,

or urine output >30 ml/hour despite adequate fluid replacement and blood transfusion over a time period of 2 hours. Group B consisted of patients with stable hemodynamics and absence of clinical signs of shock. The presence of shock was evaluated upon arrival of patients in the emergency room and was given priority if patients showed the following clinical signs: 1) hypotension <90 mmHg systolic blood pressure, 2) tachycardia >100 beats/minute, and 3) the requirements of inotropics. SIRS was present if 2 or more of following conditions were met: 1) temperature >98.60 F, 2) heart rate >90 beats/minutes, 3) respiratory rate >30 beats/minutes, 4) white blood count >12000/mm³. Sepsis was diagnosed, if all the criteria of SIRS were fulfilled in combination with a positive focus or positive blood culture.³

Evaluation and resuscitation were carried out in the emergency room. Severity of the injury was evaluated with Injury Severity Scale^{4, 5}. The operation schedule was individually adjusted to the hemodynamic status of the patient and the consideration of the associated injuries.

Patients with persistent hemodynamic instability (group A) underwent primary survey and minimal diagnostics that were followed by emergent laparotomy. Hemodynamically stable patients after adequate fluid replacement (group B) were assessed and diagnosed with ultrasonography, X-rays and if required CT scan was performed. In both the group the external stabilization with traction alone was the only procedure done for pelvic ring disruption in the preoperative and early postoperative period.

Results

The study included 19 men and 8 women with a mean age of 35.7 ±18.2 years (mean ±SF; range 15 to 65) in the 2 patients groups (Table 1). In eighteen (66.66%) patients the injuries resulted from traffic accidents. Thirty-three percent (9 patients) of all accidents resulted from fall.

Seventeen patients (62.96%) revealed persistent hemodynamic instability despite adequate resuscitation (group A). Only 10 patients (37.03%) in the study were hemodynamically stable. Patients of Group A exhibited significantly higher ISS (34.2±9.6) and lower GCS (10.5±5) compared ISS (27.6±9.4) and GCS (13.4±3.2) of group B patients Table II.

The type of pelvic injuries encountered in this study according to the classification of Tile and Pennal⁷ are shown in Table III. The intra-abdominal organ injuries and the involvement of other organ system like the head and the chest are illustrated in Table IV.

The overall mortality was 18.51% (5/27). Four 23.52% (4/17) cases died were of the Group A and one 11.11% (1/17) patients belonged to Group B. three patients died in the first 24 hours after admission because of lethal haemorrhage and the fourth one died on third postoperative day because of ARDS. The mortality that belongs to Group B patients was due to sepsis followed by MODS. Four out of five non-survivors had unstable pelvic fracture. Chest infection, wound infections, sepsis and DVT were the common complications encountered in the study.

Table I

Demographic Data

Number	n=27
Age	30.3+-18.2
Male/Female	15/12
GCS(points)	11.6+-4.6
Mortality	5(18.51%)

Table II

Severity of injury and mortality

	Group A	Group B
ISS	34.2+-9.6	27.6+-9.4
GCS	10.5+-5	13.4+-3.2
Blood Units	18+-5	10+-5
Mortality	23.52%(4/17)	11.11%(1/17)

Table III

Type of pelvic injuries related to mortality, (In parenthesis) number of nonsurvivors

Classification	Group A (n=17)	Group B (n=10)
A	6	2(1)
B1	4(3)	3
B2	2(1)	5
C	5	Nil

Table IV

Number of associated injuries

Associated Injuries	Group A (n=17)	Group B (n=10)
Abdomen		
Spleen	6	4
Liver	7	6
Gut	3	4
Bladder	1	Nil
Diaphragm	2	Nil
Head	8	4
Chest	6	3
Spine	3	2
Musculoskeletal system	10	6

Discussion

The combination of abdominal trauma and **pelvic ring injury** represents a life-threatening injury with a high mortality. Because **torrential haemorrhage** has been identified as a major cause of death, there is **widespread consensus** that successful treatment of severe haemorrhage represents the **hallmark for the survival** of these patients.^{6, 7, 10}

The outcome of patients in this study having **blunt abdominopelvic injury** with pelvic ring disruption correlates with the severity of **associated injuries** and physiological derangement on admission. The hemodynamic status **correlating** with the age and ISS of the patient at the time of presentation to the **emergency department** were most important predictors. The ISS of all the non-survived patients **remain in excess** of 40 and the age range was between 38-52 years. Age remained an **important prognostic indicator** which is also supported by the series of O'Brien DP et al.¹¹

The observed overall mortality of **18.51% (5/27)** in our study is comparable to Gustavo et al¹² and Trunkey et al¹³. This **high mortality rate** confirms the serious therapeutical problems of polytrauma patients with **pelvic ring injuries**. The bony pelvis housed major structures including viscera and **major blood vessels**, disruption and/or fracture of this protective ring can be catastrophic. **Moreover**, the force required to disrupt the pelvic ring is often of such magnitude as to **cause concomitant life-threatening injuries**. Therefore, a patient with a pelvic fracture **requires a comprehensive and rapid evaluation** for associated injuries and treatment in a **timely fashion**.^{6, 12}

The severity of associated injuries involving **other organ systems** like head and chest makes the treatment algorithm more complex.¹² **Sixty percent** of the non-survivors (3/5) had two or more systems involved apart from **abdomen and pelvis**. Statistical data

in this study depicts that severe haemorrhagic shock along with the age and ISS are the main predicting factors for mortality. In one patient there was a combination of severe liver rupture (Type IV) and Type B2 pelvic injury. One patient apart from severe abdominopelvic injury also sustained severe chest injury. In the third mortality the findings were ruptured intestine and Grade III liver injury.

Flint et al¹⁴ prospectively studied patients with severe pelvic fracture with associated hemorrhage. The mortality in this group was 5% with only one death related to uncontrollable hemorrhage from the pelvis. Mucha et al¹⁵ studied 533 patients with pelvic fractures over a 5-year period. Overall mortality was 6.4%. In 190 patients with complicated pelvic fractures, mortality was 18%. However, hemodynamically stable patients had a mortality rate of 3.4% as compared to the unstable population with a mortality rate of 42%. Almost one third of the deaths in this series were related to associated injuries and complications rather than directly to the pelvic fracture.

In polytraumatized patients the time point of pelvic fracture fixation has been controversially discussed in the past.^{8, 11, 16} Many authors have strongly recommended the emergent reduction and primary fixation of unstable pelvic fractures. Wolfgang and Karim in their study concluded the need for early fracture stabilization.⁹ For patients with closed fractures, early fixation is recommended, if possible. Fixation of pelvic fractures within 24 hours of injury has demonstrated a lower incidence of MODS and decreased length of hospital stay and has greater functional outcomes and improved mobility.¹⁶

The application of an external fixator or C-ring fixation of the posterior pelvis is a minimally invasive option; however, its application may hinder other operations in some instances.¹⁷ The aim of these maneuvers is to minimize bleeding from bony injury and to limit the volume of the pelvis, realizing that diastasis can greatly increase pelvic volume in the adult. Surgical control of pelvic hemorrhage is no longer favored, since this invariably decompresses the hematoma and may hasten bleeding with loss of tamponade of small arteries and veins.

The majority (4/5) of non-survived patients died had unstable pelvic fracture which indicates the relation of the type pelvic fracture with the outcome that has also been supported by the other series.¹⁸ Unstable pelvic fractures also had an influence over the hemodynamic status of the patients.¹⁹

Wound infections, chest infection sepsis and DVT were the common complications encountered in the study. Various sources of infection are commonly associated with pelvic trauma, including perineal wound infection and abscess, osteomyelitis, pneumonia, urinary tract infection, muscle and skin necrosis, and sepsis. Infectious complications often lead to MODS.

Conclusion

A patient with an abdominopelvic trauma is often severely injured and has other serious associated injuries. A successful treatment of severe haemorrhage represents the hallmark for the survival of these patients. A standard approach to these injuries may lead to decreased mortality. A multidisciplinary team involving general surgeons, emergency medicine physicians, orthopedic surgeons and other allied surgical specialists should be employed to ensure the highest standard of care for these patients.

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TREATMENT OF EQUINUS DEFORMITY OF FOOT IN CEREBRAL PALSY & POLIOMYELITIS

By

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ABSTRACT

Equinus deformity of foot secondary to cerebral palsy and poliomyelitis can lead to several other deformities of the body. It can be treated by various means, but the advent of the surgery i.e. lengthening of 2/3rd of tendoAchilles and transferring its 1/3rd to dorsum of foot, has introduced a new option.

We report the early results of a randomized prospective study of the said surgery in 56 patients, 30 sufferer of cerebral palsy and 26 of poliomyelitis. The patients of cerebral palsy had bilateral involvement while polio patients had unilateral involvement, so a total no. of 86 feet were operated. Both groups had the same initial management, but the polio patients needed some associated surgery. Complications included two deep infections, five superficial infections and two recurrences. Eight cases lost to follow up. The result was very good in 8 patients (16.7%), good in 20 patients (41.7%), satisfactory in 16 patients (33.3%) and poor in 4 patients (8.3%).

We consider that this surgery followed by strict physical therapy by an experienced physical therapist is the treatment of choice for selected cases of equines deformity secondary to cerebral palsy and poliomyelitis.

INTRODUCTION

Equines deformity may be due to several cause. It is one of the commonest deformities of cerebral palsy and poliomyelitis.

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