

Role of Muscle Relaxant (Tizanidine) in Painful Muscle Spasm

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Objective: To evaluate efficacy and safety of Tizanidine in painful muscle spasm of various etiologies.

Place and Duration: It was done at Rawalpindi general hospital and Holy family hospital, Rawalpindi, 1995 to July 2007.

Materials and Methods: This interventional study was carried out from July 1995 to July 2007 in outpatient department of Rawalpindi general hospital and Holy family hospital, Rawalpindi. Inclusion criteria included all the patients suffering from painful muscle spasm in back, neck, shoulder, knee or other anatomical sites with onset not more than two days prior to presentation. The patients suffering from rheumatoid arthritis, ankylosing spondylitis, osteoporosis, infective arthritis, prolapsed disc, patients with history of NSAID or analgesics intake less than 6 hours prior to receiving the first dose of study medication, severe systemic disease, uncontrolled hypertension, pregnant women and lactating mothers were excluded from the study. After initial evaluation, patients took Tizanidine three times daily for 5 days with re-evaluation on day 3 and day 6.

Results: 5300 patients comprised of 60%(n=3180) males and 40%(n=2120) females with age range of 18-75 yrs. Complete resolution of symptoms was seen in 57%(n=3021) patients while no effect was seen in 10%(n=530) patients. 14%(n=742) patients suffered from drowsiness, 2%(n=106) patients suffered from dry mouth and 2%(n=106) patients suffered from GI symptoms and nausea.

Conclusion: This study confirms that oral tizanidine is a safe, fairly effective and reliable choice for relieving painful muscle spasm.

Keywords: Painful muscle spasm, tizanidine, effectiveness, tolerability, side effects.

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Introduction

Of the numerous soft tissues that can be the locus of pain, muscle is the most frequently involved. Pain can originate primarily from the muscle tissue or secondarily from the contiguous tissue that has sustained injury. Spasm of the low back, neck and shoulder can cause significant discomfort and restriction of movement to the patient.¹

Muscle pain, spasm, swelling, and inflammation are symptomatic of strains. The precise relationship between musculoskeletal pain and spasm is not well understood. The dictum that pain induces spasm, which causes more pain, is not substantiated by critical analysis.² Most cases of simple cramps require no treatment other than rest. More prolonged or regular cramps may be treated with drugs. The goal of therapy is to increase functional capacity and relieve discomfort.³

The term "muscle relaxants" is very broad and includes a wide range of drugs with different indications and mechanisms of action. Muscle relaxants can be divided into two main categories: antispasmodic and antispasticity medications.⁴

One such muscle relaxant is Tizanidine which is an imidazole derivative and is a centrally acting α_2 -adrenergic agonist which inhibits the release of excitatory amino acids in spinal interneurons. It may also act by facilitating the action of glycine.³ In addition; Tizanidine has been shown to enhance vibratory inhibition of the H-reflex in humans and reduces abnormal co-contraction which may also, in part, contribute to antispasticity effects.⁵ Previous studies in the treatment of acute low back pain, and other conditions involving painful muscle spasm have shown Tizanidine to be effective as monotherapy and in combination with non-steroidal anti-inflammatory drugs (NSAIDs). Aim of the current study is to evaluate efficacy, safety and tolerability of tizanidine in local population.

Materials and Methods

This hospital based quasi experimental study was conducted in outpatient departments of Rawalpindi General Hospital and Holy Family Hospital from July 1995 to July 2007.

Non-probability convenient sampling was done. All the patients suffering from painful muscle spasm in back, neck, shoulder, knee or other anatomical sites with onset not more than two days prior to presentation were included in the study.

The patients suffering from rheumatoid arthritis, ankylosing spondylitis, osteoporosis, infective arthritis, prolapsed disc, patients with history of NSAID or analgesics intake less than 6 hours prior to receiving the first dose of study medication, severe systemic disease, uncontrolled hypertension, pregnant women and lactating mothers were excluded from the study.

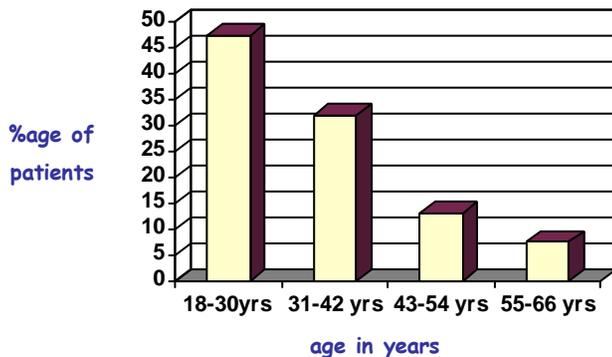
After initial evaluation, patients took Tizanidine three times daily for 5 days with re-evaluation on day 3 and day 6. Patients with severe muscle spasm were admitted. Evaluation included degree of pain according to Won-bakers faces pain rating scale. Threshold of pain was also assessed by palpation, movement, rest, at night and on awakening. Severity of muscle spasm and side effects/ tolerability of the medication were also evaluated.

At initial evaluation, 90% patients had moderate to severe pain due to spasm with pain score between 7-9, 89% experienced it on palpation, 95% complained of moderate to severe pain on movement while 66% had it at rest. Pain at night was felt by 61% and 66% complained of pain upon waking up.

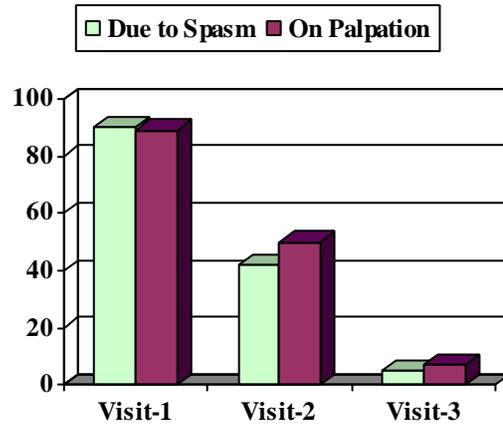
Significant reduction was noticed in pain due to spasm, on palpation, movement, rest, at night and awakening on day 3 with further pain reduction on day6. (Graph II, III and IV)

Results

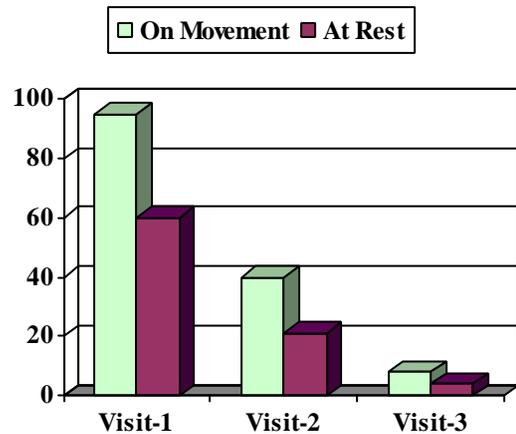
Out of a total of 5300 patients included in the study, 60 % (n=3180) were female and 40 % (n=2120) were male with an age range of 18-75 yrs. (graph 1) 35 % (n=1855) patients presented with painful muscle spasm of lower back, 30 % (n= 1590) with spasm of shoulder, 28% (n=1484) had muscle spasm at more than one site. Remaining 7 % (n=371) patients presented with spasm of neck muscles.



Graph I: Age Distribution of Patients Presenting with Muscle Spasm

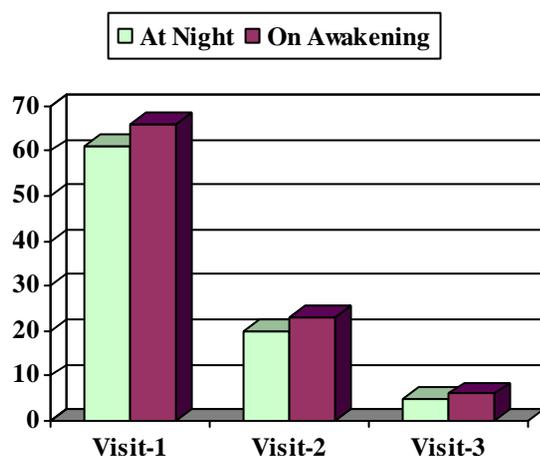


Graph II: Pain Assessment –Due To Spasm and On Palpation



Graph III: Pain Assessment –On Movement and at Rest

Regarding side effects, 14% (n=742) patients suffered from drowsiness while 2% having dry mouth. Equal number of patients (2%) complained each of nausea and other GI problems with 1 % (n=53) having dizziness.



Graph IV: Pain Assessment –At Night And On Awakening

Discussion

Wide variety of drugs can be used for the treatment of painful muscle spasm. Antispasmodics are used to decrease muscle spasm associated with painful conditions such as lower back pain. Antispasmodics can be subclassified into benzodiazepines and nonbenzodiazepines.⁴ Nonbenzodiazepines include a variety of drugs that can act at the brain stem or spinal cord level.⁶ One such drug is Tizanidine which is the focus of the current study.

In our study group majority of patients were 18-30 yrs of age and 35% patients presented with painful muscle spasm of lower back which is comparable to a similar study by Jose Alvin in Philippines in 1994 in which the mean age of the patients was 28 yrs and 27% presented with lower back muscle spasm.¹

Regarding the efficacy of Tizanidine, severity of pain decreased maximum for pain on movement (87%) followed by pain due to spasm (85%) on subsequent visits on day 6 as compared to initial evaluation on day 1. Lepisto compared Tizanidine at a dose of 2 mg three times daily for 7 days, and placebo in a double-blind study of 30 patients with acute skeletal muscle spasm. A significant change in score for muscle tension, tenderness and straight leg-raising was noted in patients who took Tizanidine compared to patients on placebo.⁷ The Korean Painful Muscle Spasm Study Group, in an open multicenter study treated 770 patients with acute painful muscle spasm in either the back, shoulder or neck using Tizanidine 1 mg three times daily for seven days. Results showed significant improvements in pain on palpation of the affected site, pain at rest, at night during movement compared to baseline.⁸ In a study by Waqstaff AJ in New Zealand, antispastic efficacy has

been demonstrated for tizanidine in placebo-controlled trials, with reduction in mean muscle tone scores of 21 to 37%.⁹

Another aspect of the study was to assess the tolerability of the drug. 14% patients complained of drowsiness followed by dry mouth (2%), nausea (2%), other GI symptoms (2%) and dizziness (1%). Study by United Kingdom Tizanidine Study Group showed that adverse effects of Tizanidine included dry mouth (45%), drowsiness (54%) and dizziness, and were seen primarily when dosages exceeded 24 mg/day. Visual hallucinations (3%) and elevated liver function tests (5%) were reversible with dosage reduction.¹⁰ Tizanidine has gastro protective effects which may favor the combination of antispasmodics with nonsteroidal anti-inflammatory drugs (NSAIDs).¹¹

Conclusion

Results of the study show that Tizanidine is effective in relieving painful muscle spasm, is safe and well tolerated. The findings of the present study conform with the previous reports of significant improvement in muscle spasm and other pain parameters by using Tizanidine as a monotherapy.¹²⁻¹⁴

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