

Novalgin in Pain and Fever

Pages with reference to book, From 226 To 227

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Abstract

Objective: Efficacy, tolerability and safety of Dipyron (Novalgin) in the management of pain and fever in children.

Setting Open, non-comparative study in Ganga Ram Hospital, Lahore.

Subjects: Children (of both sexes) aged 3 months to 12 years with oral temperature of 38.5 OC or more/complaining of pain due to various reasons.

Results: Sixty-two (66.7%) out of 93 who had fever showed good response, 24 (25.8%) showed satisfactory response and 7 (7.5%) showed unsatisfactory response to Dipyron (Novalgin).

Conclusion: Dipyron (Novalgin) in a dose of 10-15 mg/kg/dose every 6-8 hrs. is effective and safe in the treatment of pain and fever in children (JPMA 49:226, 1999).

Introduction

A wide variety of clinical disorders such as infections, trauma, collagen disease, tumors etc. may cause fever in man. Although fever may be beneficial to the defense mechanism of the patient, the overall discomfort combined with increasing probability of a febrile seizure in small children as the temperature rises, are important grounds for therapy. Indeed fever and pain are the most common reasons for seeking medical attention.

Analgesic-antipyretics are used mainly for the relief of pain and fever. The group of conventional analgesicantipyretics essentially comprise of only 3 substances: acetylsalicylic acid, Acetaminophen (paracetamol) and Dipyron (Novalgin).

Salicylates must be avoided in children with chicken pox or influenza because of risk of Reye's syndrome. They also increase the probability of metabolic acidosis in febrile children. Acetaminophen (paracetamol) is normally well tolerated but it has the smallest safety margin of all the antipyretics.

Dipyron has the lowest toxic potential of these drugs¹.

Dipyron (Novalgin) is a non-narcotic analgesic and contains metamizole as its sodium salt. It was introduced into clinical use in 1992. In addition to its analgesic and antipyretic effect it also has antispasmodic properties. Unlike acetylsalicylic acid it has no effect on platelet aggregation and therefore can be used safely in pre and post-operative patients.

The present study was done to see the clinical efficacy, tolerability and safety of Dipyron (Novalgin) in management of pain and fever in children.

Patients, Methods and Results

An open non-comparative study was undertaken in Ganga Ram Hospital, Lahore. Children (of both sexes) aged 3 months to 12 years with oral temperature of 38.5° or more and/or complaining of pain due to various reasons were included in the study. A proforma was made in which apart from basic parameters like age, sex, weight, pre-treatment assessment of pain on a scale of 0-10 depending on the severity was recorded and in case of fever initial temperature was recorded. After establishing the diagnosis each patient was given Novalgin in a dose of 10-15 mg/kg/dose 6 to 8 hourly for a period of three days. Pain and/or fever charting was done 6 hourly in their respective charts. Response to therapy was assessed at the end of study. It was labeled as good when no symptoms were present on day 2,

satisfactory when symptoms and signs were 50% less than on the day of admission and failure when both signs and symptoms persisted.

A total of 100 patients participated in the study of which 51 were males and 49 females. Ninety-three children were suffering from fever and seven from pain due to various reasons. Out of 93 who had fever 62 (66.7%) showed good response, 24 (25.8%) satisfactory response and 7 (7.5%) unsatisfactory response to Dipyron (Novalgin). Of nine cases with pain 4 (57%) showed good and 3 (43%) satisfactory response to the drug.

For purpose of analysis, cure and improvement have been merged together and termed Clinical Success Rate, which was 92.5% for fever and 100% for pain. Only 4.3% reported vomiting, which was mild in nature.

Comments

The efficacy of Dipyron (Novalgin) in the management of pain and fever in this study showed 100% and 92% clinical response respectively. Different comparative studies have proved Dipyron (Novalgin) to be a more effective analgesic/antipyretic agent than acetylsalicylic acid and paracetamol^{2,3}.

In a controlled study of 267 patients with postepisiotomy pain, to assess the analgesic efficacy of oral treatment with Dipyron in comparison with acetylsalicylic and a placebo, pain relief with dipyron was more rapid and more effective than with acetylsalicylic acid².

In a multi-center study Dipyron was compared to paracetamol in a total of 90 patients with post surgical dental pain, Dipyron offered faster and longer-lasting pain relief in more patients than Acetaminophen (paracetamol)³.

The same study also documented the use of Dipyron or Acetaminophen (paracetamol) in comparison with a placebo in 259 patients with post-episiotomy pain. Dipyron was again superior to Acetaminophen (paracetamol) in rapidity and duration of analgesic effective in these patients³. Similar results were obtained in comparative studies between dipyron and other antipyretic agents⁴⁻⁶. In a double blind clinical study comparing unit doses of 500 mg dipyron with 100 mg nimesulide and 500 mg acetylsalicylic acid in which dipyron was more effective than acetylsalicylic acid⁴.

In another comparative double blind study in 53 patients with typhoid fever, Acetaminophen (paracetamol) or Dipyron was given alongwith anti-typhoid medication. In patients given Dipyron, the reduction in temperature was significant ($p < 0.05$) after 30 min and those given Acetaminophen (paracetamol), it was significant ($p < 0.05$) after 1 hour. The sum of the reduction in temperature at all times significantly favoured patients who had been given dipyron⁵. In another study involving 120 patients (children 4-10 years.) the drug was compared to Acetaminophen (paracetamol) in reducing fever. Dipyron (Metamizol) proved to be significantly more effective than Acetaminophen (paracetamol) in lowering temperature⁶.

A multi-center study undertaken in seven countries over a population of 22.2 million to assess the risk of agranulocytosis and aplastic anemia in relation to drug use in general with particular interest in dipyron. The estimated excess risk of agranulocytosis attributable to dipyron use in approx. 1/million/week or less whereas on the basis of available studies the risk of G.I. bleeding with acetylsalicylic acid is estimated to be approx. ¹⁰ times higher than risk of aganulocytosis with dipyron⁷⁻¹¹.

The main disadvantage of Acetaminophen (paracetamol) is liver toxicity, because of its moderate analgesic effect and persistence of symptom patients may use doses higher than those recommended thus giving rise to liver toxicity¹²⁻¹⁴.

Children suffering from fever and pain should be administered analgesic/antipyretic agents which are

effective and safe. The association between ASA use and the risk of Reye's Syndrome has led to its more restricted use in children. This has resulted in the routine administration of Acetaminophen (paracetamol) and Dipyrrone, which has an edge over Acetaminophen (paracetamol), in its analgesic and antipyretic activity.

It is thus suggested that dipyrrone in a dose of 10-15 mg/kg every 6 to 8 hours is effective and safe for treating pain and fever in children.

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