

Incidence of adverse drug reactions induced by *N*-acetylcysteine in patients with acetaminophen overdose

Sa'ed H Zyoud¹, Rahmat Awang¹,
Syed Azhar Syed Sulaiman², Waleed M Sweileh³ and
Samah W Al-jabi²

Abstract

Background: Intravenous *N*-acetylcysteine (IV-NAC) is widely recognized as the antidote of choice for acetaminophen overdose. However, its use is not without adverse drug reactions (ADR) that might affect therapeutic outcome or lead to treatment delay. **Objective:** the aim of this study was to investigate the type and incidence of ADR induced by IV-NAC in patients treated for acetaminophen overdose. **Methods:** This is a retrospective study of patients admitted to the hospital for acute acetaminophen overdose over a period of 4 years (1 January 2005 to 31 December 2008). The primary outcome of interest in this study was the occurrence of ADR during NAC administration. Pearson chi-square test or Fisher's exact test, student's *t* test, and Mann-Whitney *U* test were used in univariate analysis. SPSS 15 was used for data analysis. **Results:** Two hundred and fifty five patients were studied. Different types of ADR were observed in 119 (46.7%) cases. Of those patients, 83 (69.7%) had been treated with IV-NAC versus 36 (30.3%) who had not ($p < .001$). The following ADR were significantly associated with IV-NAC administration: vomiting ($p = .001$), flushing ($p < .001$), rash ($p < .001$), pruritus ($p < .001$), chest pain ($p = .001$), bronchospasm ($p = .03$), coughing ($p = .01$), headache ($p = .001$), dizziness ($p < .001$), convulsion ($p = .03$), and hypotension ($p = .001$). ADR were mild in 54 (43.2%), moderate in 17 (13.6%), and severe in 12 (9.6%) patients. There were no ADR in 42 (33.6%) patients. Comparative results of the characteristics of patients who reacted to IV-NAC and non-reactors showed that patients with ADR had no significant difference in age, gender, ethnicity, amount ingested, latency time, and acetaminophen level than nonreactors. **Conclusion:** ADR to IV-NAC were common among patients with acetaminophen overdose, but mostly minor and all reported adverse reactions were easily managed.

Keywords

acetaminophen, adverse drug reaction, *N*-acetylcysteine, overdose

Introduction

Acetaminophen (paracetamol) is one of the most widely used drugs worldwide.¹ In therapeutic doses, acetaminophen has an excellent safety profile. However, in large doses, acetaminophen can cause liver impairment.¹⁻³ In fact, acetaminophen overdose is one of the leading causes of liver failure in the western world.²⁻⁴ Acetaminophen remains the most common means of pharmaceutical poisoning in the Eastern world including Malaysia.^{5,6} Management of patients with acetaminophen overdose includes the use of

¹ WHO Collaborating Centre for Drug Information, National Poison Centre, Universiti Sains Malaysia (USM), Penang, Malaysia

² Clinical Pharmacy program, School of Pharmaceutical Sciences, Universiti Sains Malaysia (USM), Penang, Malaysia

³ College of pharmacy, An-Najah National University, Nablus, Palestine

Corresponding author:

Sa'ed H Zyoud, Clinical Toxicology, National Poison Centre, Universiti Sains Malaysia (USM), Penang, Malaysia.

E-mail: saedyoud@najah.edu