

A dangerous adverse event in the use of dabigatran

Manuel Monti,¹ Giovanni Maria Vincentelli,² Francesco Borgognoni,¹ Giuseppe Murdolo,¹ Feliciano Menghini¹

¹Emergency Department, AUSL UMBRIA1, Assisi (PG); ²Emergency Department, Fatebenefratelli Hospital, Roma, Italy

Letter to the Editor

In recent years, the new oral anticoagulants, direct inhibitors of the X factor (rivaroxaban, apixaban) or of the thrombin (dabigatran), have consolidated their role in the prevention of venous thromboembolism (in case of total hip replacement) as well as in the cardioembolic stroke prophylaxis (in patients with non-valvular atrial fibrillation). Moreover, more recently, rivaroxaban and apixaban are indicated in the treatment and prevention of recurrent deep vein thrombosis and pulmonary embolism.¹

The most serious side effect is the gastro intestinal bleeding that, however, can be often avoided by a careful assessment of the individual patient.²

Here, we draw attention to an extremely rare side effect, perhaps one of the first cases described in the literature, occurred in a patient with non-valvular atrial fibrillation treated with dabigatran 110 bid for thrombo embolic prophylaxis.

We describe the case of a patient, male, 88 years old, transported to the Emergency Department of the Assisi Hospital with intense dyspnea associated with tirage and corneage. These clinical symptoms arose two minutes after taking one capsule of 110 mg dabigatran that the patient accidentally smashed in the mouth.

Blood tests were performed [white blood cell

(WBC) 10,830/mmc, neutrophils 74.8%, lymphocytes 18.8%, monocytes 5.6%, eosinophils 0.6%, basophils 0.2% C-reactive protein 0.19 mg/dL, electrolytes normal] and a chest X-ray resulted normal. Laboratory findings showed that WBC count and C-reactive protein were slightly increased (Table 1). He had a medical history of hypertension (furosemide 25 mg twice daily and olmesartan 20 mg once daily) for 10 year and diabetes mellitus treated with oral hypoglycemic agents for 7 years. The patient had permanent atrial

Table 1. Blood tests.

White blood cell	10,830	mmc	4.50-10.80
Red blood cell	5.39		4.60-6.20
Hemoglobin	16.7		13.50-18.00
Hematocrit	45.4		40.0-50.0
MCV	84.2		80.0-94.0
MCH	31		27.0-33.0
MCHC	36.8		33.0-37.0
RDW	12.2		11.5-16.0
Neutrophils %	74.8		40.0-75.2
Lymphocytes %	18.8		20.5-51.1
Monocytes %	5.6		0.0-13.0
Eosinophils %	0.6		0.5-6.0
Basophils %	0.2		0.15-2.0
Platelet	152		130-400
Glucose	106	mg/dL	60-110
Creatinine	0.9	mg/dL	0.70-1.20
Blood urea nitrogen	37	mg/dL	12.5-50.0
Sodium	140	mmol/L	136-145
Potassium	3.5	mmol/L	3.5-5.1
Calcium	9.4	mg/dL	8.6-10.2
Aspartate transaminase	25	U/L	0-40
Alanine transaminase	16	U/L	0-41
Creatine kinase	205	U/L	0-190
C-reactive protein	0.19	mg/dL	0.5-1.0

MCV, mean corpuscular volume; MCH, mean corpuscular hemoglobin; MCHC, mean corpuscular hemoglobin concentration; RDW, red cell distribution width.

Correspondence: Manuel Monti, AUSL UMBRIA1 U.O. PS/118, via V. Muller 1, 06081 Assisi (PG), Italy.
E-mail: montimanuel@tiscali.it

Key words: Dabigatran; edema of the vocal cords; frail patients.

Received for publication: 29 July 2015.
Revision received: 24 September 2015.
Accepted for publication: 5 November 2015.

This work is licensed under a Creative Commons Attribution NonCommercial 4.0 License (CC BY-NC 4.0).

©Copyright M. Monti et al., 2016
Licensee PAGEPress, Italy
Italian Journal of Medicine 2016; 10:250-251
doi:10.4081/ijm.2015.629

fibrillation and, for about two months, had started therapy with dabigatran (90 mg twice daily).

After an unsuccessfully initial treatment with steroids (hydrocortisone 1000 mg endovenously and aerosols beclomethasone) and β -adrenergic aerosol, the patient was treated with epinephrine (1 mg 1 fL for aerosol) resulting in clinical improvements while persisting a light dyspnea for some hours.

After the adrenaline treatment, the patient was subjected to laryngoscopy that allowed revealing an edema of the vestibule palatine and extensive edema of the vocal cords with a consequent reduction of the airspace.

The clinical scenario described above is the result of an allergic reaction to one or more component of the structure of the drug capsule. In the next months, the

patient will be submitted to allergy tests in order to point out the allergen responsible of this severe reaction.

Finally, we found appropriate, especially in patients who have difficulty swallowing, to have the greatest attention to the correct method of taking the drug.

References

1. Larsen TB, Rasmussen LH, Skjøth F, et al. Efficacy and safety of dabigatran etexilate and warfarin in “real-world” patients with atrial fibrillation: a prospective nationwide cohort study. *J Am Coll Cardiol* 2013;61:2264-73.
2. Bauersachs RM. Managing venous thromboembolism with novel oral anticoagulants in the elderly and other high-risk patient groups. *Eur J Intern Med* 2014;25:600-6.

Non-commercial use only