

DIALYSIS. ANAEMIA

FP678 **IMPACT OF EUROPEAN MEDICINES AGENCY
RECOMMENDATIONS FOR ALLERGIC REACTIONS TO
INTRAVENOUS IRON-CONTAINING DRUGS IN DIALYSIS
CENTERS OF LOMBARDY REGION**

Rodolfo Rivera¹, Davide Guido², Lucia Del Vecchio³, Andrea Galassi⁴,
Marco D'amico⁵, Enzo Corghi⁶, Donatella Spotti⁷, Corrado Camerini⁸,
Claudio Pozzi⁶, Giovanni Cancarini⁸, Francesco Locatelli³ and
Giuseppe Pontoriero³

¹San Gerardo Hospital, Nephrology and Dialysis Unit, Milan, Italy, ²University of Pavia, Department of Brain and Behavioural Sciences, Medical and Genomic Statistics Unit, Pavia, Italy, ³A. Manzoni Hospital, Nephrology and Dialysis Unit, Lecco, Italy, ⁴Desio Hospital, Nephrology and Dialysis Unit, Desio, Italy, ⁵Sant'Anna Hospital, Nephrology and Dialysis Unit, Como, Italy, ⁶Bassini Hospital, Nephrology and Dialysis Unit, Cinisello Balsamo, Italy, ⁷San Raffaele Hospital, Nephrology and Dialysis Unit, Milan, Italy, ⁸Spedali Civili Brescia and University of Brescia, Nephrology and Dialysis Unit, Brescia, Italy

Introduction and Aims: European Medicines Agency (EMA) has recommended measures to be taken to manage and minimize the risk of hypersensitivity reactions to

all intravenous iron (FeIV) drugs available across Europe. The aim of this survey was to analyze the effects on FeIV clinical management after the introduction of this recommendations among hemodialysis centers (HDC) in Lombardy Region.

Methods: A web-questionnaire was sent to all 117 HDC in Lombardy. Items concern HDC types (hospital: HC and peripheral: CAL), and their organization: presence of intensive care unit (ICU), emergency trained staff, iron used, IV administration modalities, side effects, and variations on FeIV therapy between 2013 and 2014 (α FeIV). Linear regression model was used to analyze the raw "focus" effects of HDC types on outcome and a forward stepwise procedure to assess the confounding impact by percentage variation ($\alpha\beta\%$) of the effect.

Results: Survey response rate was 73.5%. FeIV therapy was used in 69.1% (range 11%-100%) of patients and after EMA's recommendation indications were reduced by 12.6% (α -FeIV%). No severe adverse reactions were reported. Differently from CAL, HC had larger number of ICU (97.2 vs 20%, OR=128.8, $P<0.001$), emergency trained staff (97.2 vs 61.2%, OR=22.2, $P<0.001$) and facilities (91.7 vs 58%, OR=7.8, $P<0.001$). Linear regression model demonstrated a significant raw "focus" effect of HDC types on α -FeIV% ($\beta=19.6$, $P<0.001$). Non-significant association were found in ICU-adjusted model ($\beta=6.7$, $P=0.199$) and all-confounding adjusted model ($\beta=5.6$, $P=0.337$).

Conclusions: The absence of serious hypersensitivity reactions confirms the safety of FeIV products and under-utilization of the FeIV therapy was detected. EMA's recommendations were associated with a significant drop in FeIV therapy prescriptions in CAL compared to HC. However this effect was suppressed by the presence of intensive care units.