

Potential side effects from prescribed therapy: Consequences of not informing patients

Pettersen TR^{1,2}, Schjøtt J^{2,3}, Allore H^{4,5}, Bendz B^{6,7}, Borregaard B^{8,9}, Fridlund B^{1,10}, Hadjistavropoulos H¹⁰, Larsen AI^{2,12}, Nordrehaug JE², Rasmussen TB¹³, Rotevatn S¹, Valaker I¹⁴, Wentzel-Larsen T¹⁵⁻¹⁷, Norekvål TM^{1,2}.

On behalf of the CONCARD Investigators.

¹Department of Heart Disease, Haukeland University Hospital, Norway

²Department of Clinical Science, University of Bergen, Norway

³Department of Medical Biochemistry and Pharmacology, Haukeland University Hospital, Norway

⁴Department of Internal Medicine, Yale School of Medicine, USA

⁵Department of Biostatistics, Yale School of Public Health, USA

⁶Department of Cardiology, Oslo University Hospital, Norway

⁷Institute of Clinical Medicine, University of Oslo, Norway

⁸Department of Cardiology, Odense University Hospital, Denmark

⁹Department of Clinical Research, University of Southern Denmark, Denmark

¹⁰Centre of Interprofessional Collaboration within Emergency Care (CICE), Linnaeus University, Sweden

¹¹Department of Psychology, University of Regina, Canada

¹²Department of Cardiology, Stavanger University Hospital, Norway

¹³Department of Cardiology, Gentofte University Hospital, Denmark

¹⁴Faculty of Health and Social Sciences, Western Norway University of Applied Sciences, Førde, Norway

¹⁵Centre for Clinical Research, Haukeland University Hospital, Norway

¹⁶Centre for Child and Adolescent Mental Health, Eastern and Southern Norway, Norway

¹⁷Norwegian Centre for Violence and Traumatic Stress Studies, Norway

Abstract

Background: Healthcare providers are commonly disinclined to inform patients about potential adverse drug reactions (ADRs) from prescribed therapy to avoid increasing the incidence of ADRs through the nocebo effect. However, patients need information on all aspects of prescribed therapy to make informed decisions about their treatment process and take ownership of their care.

Purpose: To determine whether patients received information about potential ADRs from prescribed therapy before hospital discharge after percutaneous coronary intervention (PCI), and to determine whether provision of information about ADRs influenced the incidence of self-reported ADRs.

Methods: CONCARD^{PCI}, a prospective multicentre cohort study including 3417 patients following PCI, was conducted between June 2017 and May 2020 at seven large referral PCI

centres in Norway and Denmark. Clinical data were collected from patients' medical records. Socio-demographic characteristics were self-reported during index hospitalization after PCI. Two questions from the Heart Continuity of Care Questionnaire were used to determine if information about potential ADRs was provided before hospital discharge. De novo created questions were used to determine if patients experienced ADRs from prescribed therapy. Questionnaires were distributed two- (T1), six- (T2), and twelve months (T3) after hospital discharge. Chi-square test was applied to scrutinize the aims.

Results: The majority were men (78%), with a mean age of 66 years (SD 11, range 20–96 years). Before hospital discharge, 59% reported being informed of potential ADRs from prescribed therapy. The incidence of ADRs were significantly lower for those who were informed of potential ADRs (36%, 43% and 33% at T1-T3 respectively) compared to those who were not informed (51%, 58% and 49% at T1-T3 respectively) ($p < 0.001$ for all comparisons).

Conclusion: Patients informed about ADRs had lower incidences of self-reported ADRs from prescribed pharmacotherapy.