Journal of Clinical Lipidology (2018) ■, ■–■

Journal of Clinical Lipidology

Original Article

Treatment-related and health-related quality of life in lipoprotein apheresis patients

V. De Gucht, PhD*, K. Cromm, MSc, A. Vogt, MD, U. Julius, MD, B. Hohenstein, MD, R. M. Spitthöver, MD, W. Ramlow, MD, V. J. J. Schettler, MD, S. Maes, PhD

Department of Health and Medical Psychology, Leiden University, Leiden, The Netherlands (Drs De Gucht and Maes); Fresenius Medical Care, Bad Homburg, Germany (Dr Cromm); Stoffwechselambulanz, Medizinische Klinik und Poliklinik IV, Klinikum der Universität München, München, Germany (Dr Vogt); Lipidology, Department of Internal Medicine III, University hospital at the Technische Universität Dresden, Dresden, Germany (Drs Julius and Hohenstein); Dialysezentrum Essen, Essen, Germany (Dr Spitthöver); Apheresis Center Rostock (ACR), Rostock, Germany (Dr Ramlow); and Nephrologisches Zentrum Göttingen, Göttingen, Germany (Dr Schettler)

KEYWORDS:
Health care evaluation;
Health-related quality of life;
Lipoprotein apheresis;
Physical complaints;
Scale development;
Treatment-related quality of life

BACKGROUND: There is evidence for beneficial effects of lipoprotein apheresis (LA) in terms of reduction of cardiovascular events and interventions, but quality of life (QOL) in LA patients has only been explored in small samples.

OBJECTIVE: In this study, both LA- or treatment-related and health-related QOL (HRQOL) were assessed in 206 LA patients.

METHODS: Mental and physical HRQOL of the LA patients was assessed by means of the SF-12 as well as the EQ-5D. Physical complaints were assessed by the Patient Health Questionnaire–15 and LA- or treatment-related QOL by the Apheresis Quality of Life Form, developed for this study.

RESULTS: Comparison with general population norms showed that LA patients scored significantly lower on HRQOL and significantly higher on physical complaints. A higher perceived impact of the treatment proved to have a significant negative association with HRQOL and a positive one with physical complaints.

CONCLUSION: Previous studies reported higher levels of QOL in LA patients. This study showed that treatment-related QOL contributes to HRQOL and physical complaints in LA patients. While many patients do not experience LA as a real burden and report positive effects of the treatment, there is also an important group of patients for whom this is not the case. Although the impact on QOL of LA patients does most probably not outweigh the cardiovascular benefits of the treatment, it is important to

Conflict of interest: Dr D.G.V. and Dr M.S. received a grant from Fresenius Medical Care (FMC) to design the present study, analyze, interpret, and report the data in an independent way and to submit the article for publication. Final decisions in every stage were taken by them. FMC was not involved in this process except for the participation of C.K. as a co-author. They have no other financial interests. C.K. is employed by FMC. Dr V.A. has received speaker honoraria for presentations and advisory board activities by Aegerion, Amgen, B. Braun, FMC, Genzyme, a Sanofi company, Kaneka, Merck Sharp & Dohme. Dr V.A. also received research support from Merck Sharp & Dohme. Dr H.B. was and Dr J.U. is the head of one of the participating LA centers. Dr J.U. got honoraria for lectures from Aegerion, Amgen, FMC, Kaneka, Sanofi and for lipidologic evaluations from FMC. Dr H.B. received honoraria for presentations and advisory board activities and research grants from Amgen, B. Braun Avitum, FMC, Kaneka Pharma Europe, Miltenyi Biotec, and Sanofi/Regeneron. Dr S.R.M. has no financial interests to declare. Dr R.W. is the head of 1 participating LA center. Dr R.W. is an employee of Nephrocare Rostock GmbH. He received honoraria for presentations or advisory board activities by Amgen, B. Braun, FMC, Kaneka, Sanofi/Regeneron. Dr S.V.J.J. has no financial interests to declare.

* Corresponding author. Department of Health and Medical Psychology, Leiden University, PO BOX 9555, 2300 RB Leiden, The Netherlands.
E-mail address: degucht@fsw.leidenuniv.nl

Submitted October 20, 2017. Accepted for publication May 10, 2018.

https://doi.org/10.1016/j.jacl.2018.05.008

screen treatment-related QOL in LA patients to optimize care in a personalized way. Future research is needed to compare QOL in LA with non-LA patients with similar medical conditions.

Introduction

Lipoprotein apheresis (LA) is a long-term and expensive treatment and the evidence for its effectiveness in terms of prevention of cardiovascular events is based on a limited number of studies.[1,2] In several European countries and especially Germany, LA is a well-accepted and commonly used treatment for homozygous familial hypercholesterolemia. Generally, in all patients at high and very-high risk, a documented maximized low-density lipoprotein cholesterol (LDL-C)–lowering diet and drug therapy for 12 months failing its therapeutic LDL-C targets should lead to the commencement of LA. In addition, an elevation of lipoprotein(a) (Lp(a)) levels ≥ 60 mg/dL (≥120 nmol/L), in the presence of normal LDL-C levels, and (clinically and by an imaging technique) documented progressive cardiovascular disease has been included into the list of reimbursed indications for LA.[3] Indications and thresholds differ however from country to country.[2] In the United States, LA treatment is only offered to coronary heart disease (CHD) or peripheral vascular disease patients with an LDL-C level at or above 160 mg/dL and to patients without CHD with an LDL-C level at or above 300 mg/dL, who showed an inadequate response to at least 6 months of diet, exercise, and the maximum tolerated dose of cholesterol-lowering medication[4,5]

A recent systematic review[2] explored the benefits of LA for patients with familial hypercholesterolemia. The studies included in this review show a range for mean LDL-C reduction by a single apheresis session of 57%–75%. In addition, based on 4 studies, the risk of cardiovascular events as well as the number of cardiovascular interventions appeared to be significantly reduced by LA treatment. None of the studies included in this review evaluated however the quality of life (QOL) of LA patients.

The quality of earlier studies on QOL in LA patients is poor.[6] A Norwegian study[7] evaluated patient satisfaction with LA treatment with a VAS-scale ranging from 0 to 10 in only 3 LA patients with heterozygous familial hypercholesterolemia. Another study[8] assessed health-related QOL (HRQOL) by means of the SF-36 in 7 patients with homozygous hypercholesterolemia treated with LA and concluded that the QOL of these patients, except for 2 patients who also had a history of early-onset cardiovascular disease, was comparable to a healthy reference population. Witschas[9] measured HRQOL using a German questionnaire for patients with chronic disease, the Quality of Life Profile for the Chronically Ill as well as anxiety and depression using the Hospital Anxiety and Depression Scale (HADS). Comparing data from 23 patients who were offered LA on a weekly basis, 32 hospitalized CHD patients, and 31 hemodialysis (HD) patients, no difference was found between LA patients and CHD patients with respect to mental and social QOL, anxiety, or depression, while LA patients scored higher on physical HRQOL. LA patients scored higher than HD patients on mental, social, and physical HRQOL and lower on depression. The author concluded that LA patients have a good HRQOL without however using normative data. By contrast, Stasiewski et al[10] conducted a study in which they investigated anxiety and depression, measured by the HADS, and HRQOL, measured by the SF-12, in 41 LA patients, 41 HD patients, and 20 platelet donors. All LA patients were characterized by hyperlipidemia and with 1 exception also by documented atherosclerosis. HD patients reported a significantly lower physical and mental HRQOL and higher anxiety and depression levels compared with the general population norm. In a study conducted at the university hospital Berlin Charité,[11] the SF-36, measuring physical and mental HRQOL, and the beck depression inventory were administered to 29 LA patients, together with a newly developed apheresis QOL questionnaire, measuring treatment-related QOL. All LA patients had prior histories of cardiovascular events and/or cerebrovascular disease, and a diagnosis of hypercholesterolemia and hyperlipoproteinemia(a). The LA patients scored significantly lower on mental HRQOL and higher on depression than the general population, but no differences were found for physical HRQOL. When asked about their physical and mental status since the start of apheresis, most of these patients reported an improvement. The authors concluded that LA reduced physical complaints and was well tolerated by patients without major problems or negative effects on QOL. Finally, a prospective British study[12] showed an increase of physical HRQOL, measured by the SF-36, from preapheresis to 3 months of LA treatment in a sample of 20 patients with refractory angina and raised Lp(a) > 500 mg/L.

Systematic research on QOL in larger, more representative populations of LA patients is lacking. In addition, it can be questioned whether the existing studies are a good indicator of the impact of LA treatment since HRQOL questionnaires or measures of psychological symptoms such as the SF-36, SF-12, the Quality of Life Profile for the Chronically Ill, the beck depression inventory, or the HADS rather assess how patients experience consequences of the underlying medical condition or disease than how they specifically experience the treatment. The Berlin study[11] is the only study using a specific LA treatment–related questionnaire, but the study remains a pilot study in a relatively small group of LA patients. The British study[12] suggests that LA treatment improves physical HRQOL, but this study is also small and conducted in a selective group of patients.