






## RESEARCH SUBMISSIONS

# Improving distress perception and mutuality in migraine caregivers after 6 months of galcanezumab treatment

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## Abstract

**Objective:** This prospective cohort, real-life study aimed to evaluate whether galcanezumab, a monoclonal antibody anti-calcitonin gene-related peptide (CGRP) ligand, can reduce caregivers' distress and improve their mutuality with patients.

**Background:** Migraine is a highly disabling chronic disease that negatively impacts patients' and often their relatives' lives, occurring during an active phase of life with direct consequences on leisure- and work-related activities. The figure of caregiver is crucial in several neurological conditions but poorly accounted for in migraine care so far. Studies on monoclonal antibodies against the CGRP pathway, recently introduced as migraine-preventive treatments, demonstrated that they significantly reduce migraine frequency and disability in the first weeks of treatment.

**Methods:** Consecutive patient-caregiver dyads were evaluated at baseline and after 6 months of treatment with galcanezumab (V6) at our headache center from September 2020 to September 2021. Enrolled patients were requested to report their monthly migraine days, monthly intake of acute medications, attack pain intensity (on the Numeric Rating Scale), concomitant preventives, and disability questionnaires (Headache Impact Test, Migraine Disability Assessment). Each dyad filled in the Mutuality Scale to check their reciprocity; moreover, the Relatives' Stress Scale was used to detect caregivers' distress.

**Results:** We enrolled 27 patient-caregiver dyads. At 6 months, migraine burden significantly improved with reductions in monthly migraine days (falling from 14.8 [SD = 4.8] days by 10.3 [SD = 4.8] days; 95% CI: 8.4, 12.2;  $p < 0.001$ ) and Migraine Disability Assessment scores (lowering from 83.6 [SD = 46.7] by 71.5 points [SD = 49.3]; 95% CI: 51.2, 91.9;  $p < 0.001$ ). From baseline to month 6, the caregiver Relatives' Stress Scale score significantly decreased (falling from 20.7 [SD = 13.7] by 6.5 [SD = 14.1] points; 95% CI: 0.8, 12.2;  $p = 0.027$ ), while the Mutuality Scale's caregiver total score increased (from 3.04 [SD = 0.61] by 0.29 [SD = 0.49] points; 95% CI: -0.508, -0.064;  $p = 0.014$ ).

**Abbreviations:** CGRP, calcitonin gene-related peptide; mAbs anti-CGRP, monoclonal antibodies against CGRP; MS, Mutuality Scale; RSS, Relatives' Stress Scale.

Luisa Fofi and Claudia Altamura contributed equally to the manuscript.

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**Conclusions:** Our findings preliminarily demonstrated that patients' migraine improvement after 6 months of galcanezumab treatment could be favorably perceived by caregivers, significantly reducing their distress with better reciprocity within the dyad.

**KEYWORDS**

burden, caregiver, distress, migraine, mutuality, reciprocity

## INTRODUCTION

Migraine is a highly disabling chronic disease that negatively impacts patients' leisure- and work-related activities, and the effects often go beyond patients and directly involve their families.<sup>1</sup>

While in several neurological conditions the caregiver figure is highly considered, it has not been much regarded so far in defining the migraine burden.<sup>2,3</sup> The literature shows that chronic diseases could be associated with huge family burden; caregivers are at risk of developing psychological distress and having their financial and social aspects impacted in relation to patients' disease duration and disability.<sup>4,5</sup>

Quantifying family impact is important for mitigating migraine burden. In clinical practice there are no specific scales recognized worldwide for this purpose. In other chronic neurological conditions like dementia, Parkinson disease, and multiple sclerosis, the caregivers' burden has been widely measured by the Relatives' Stress Scale (RSS).<sup>6</sup> In patients who have had a stroke, the reduction of mutuality—which represents the positive relationship between a caregiver and a care-receiver—has been investigated by the Mutuality Scale (MS).<sup>7,8</sup> However, in contrast to other neurologic diseases that impair physical independence on a constant basis, migraine attacks can render patients unable to lead a normal life even though interictally they are physically healthy. Moreover, in the interictal phase they may feel good, yet deprive themselves nevertheless of social activities out of fear of triggering an attack, inevitably impacting partner, social, and familial activities.

The recent introduction of monoclonal antibodies (mAbs) against calcitonin gene-related peptide (anti-CGRP) as migraine-preventive treatments has changed the course of migraine, because they significantly reduce attack frequency and disability, starting at the first weeks of treatment<sup>9-11</sup> and beyond.<sup>12</sup>

This study aims to investigate whether galcanezumab, a mAbs to the CGRP ligand, can also reduce caregivers' distress and improve mutuality as perceived by patients and caregivers after 6 months of treatment. We hypothesized that the improvement in migraine burden could be associated with a decrease in RSS and an increase in dyad MS scores.

## METHODS

### Design and data collection

This prospective, cohort, real-life study consecutively enrolled patients with migraine who received galcanezumab for the first time for treatment at our Campus Bio-Medico University headache center

as well as their caregivers from September 2020 to September 2021. This is a preliminary substudy of the GARLIT study approved by the ethical committee of Campus Bio-Medico University of Rome (No. 30/20 OSS ComEt CBM). All participants provided written, informed consent.

Collection of data relative to migraine characteristics and related disability is described elsewhere.<sup>11</sup> For the present observation, we also considered the sociodemographic characteristics of caregivers. We identified a caregiver as any member of the patient's family or social circle taking care of the patient during pain attacks and attack prodrome and postdromes. Patients and caregivers were evaluated at baseline and after 6 months of treatment with galcanezumab. Galcanezumab was administered monthly by subcutaneous injections with a loading dose of 240mg the first month then 120mg monthly.

At baseline and 6 months, migraine disability was assessed by the Migraine Disability Assessment scale<sup>13</sup> and the Headache Impact Test.<sup>14</sup> Patient caregiver distress was measured by the RSS,<sup>6</sup> a self-rated 15-item scale; each item is assessed on a 5-point scale from 0 to 4 (never, rarely, sometimes, frequent, always): the higher the score, the higher the degree of stress (range 0–60).

At the same intervals, patients and caregivers filled out the Mutuality Scale (MS),<sup>7,8</sup> which explores the reciprocity, intended as the positive feeling and relationship between patient and caregiver. It is composed of 15 items grouped in 4 domains (love, shared pleasurable activities, shared values, and reciprocity). Each item's score is based on a scale of 5 points, from 0 (not at all) to 4 (a great deal). The total MS score, that is, the mean of all item scores, ranges from 0 to 4: the higher the score, the greater the mutuality. The reliability of the RSS and MS scales has been previously established.<sup>6,8</sup>

The collected data were available for all participants. There were no missing data.

### Statistical analyses

This is a primary analysis of the collected data from a convenience sample. The sample size was determined based on a similar preliminary report on the same topic.<sup>15</sup> No statistical power calculation was conducted. Statistical analyses were performed with SPSS version 27.0 (SPSS Inc., Chicago, IL, USA). Data distribution was visually assessed with histograms. The interval variables were expressed as means with standard deviations (SDs). Paired *t*-tests were used to analyze the variable changes over time. All tests were two-tailed. Statistical significance was set as  $p < 0.05$ .

## RESULTS

A total of 27 patients affected by migraine without aura (14 episodic [52%], 13 chronic [48%]) and their caregivers were enrolled in the study. Patients' and caregivers' characteristics and migraine details are summarized in Table 1. All patients had previously not responded to at least 3 preventives; 20 patients (74%) were taking concomitant migraine preventive medications. Migraine attack details and disability score improvement are reported in Table 2.

At month 6, caregivers' mean RSS significantly decreased from baseline (from 20.7 [SD = 13.7] to 13.7 [SD = 12.4];  $p = 0.027$ ), and their MS total score increased (from 3.04 [SD = 0.61] to 3.33 [SD = 0.41];  $p = 0.014$ ). Moreover, we observed no changes in caregivers' love domain ( $p = 0.130$ ), but saw improvements in the shared pleasurable activities ( $p = 0.020$ ), shared values ( $p = 0.035$ ), and reciprocity ( $p = 0.035$ ) domains. The MS total score of patients did not significantly change from baseline to month 6 (from 3.12 [SD = 0.37] to 3.16 [SD = 0.57];  $p = 0.750$ ), and no significant variations were detected in the four domains (Table 2).

## DISCUSSION

Migraine affects mostly young and middle-aged people with a direct impact on patients' life.

However, migraine largely extends beyond patients: 50% of migraine caregivers reported that their social and leisure activities were strongly affected by the patient's own migraine burden.<sup>16</sup>

TABLE 1 Patients' and caregivers' characteristics and migraine details

Patients (n)	27
Age, years, mean (SD)	48.5 (9.7)
Female, n (%)	26 (96)
Disease duration, years, mean (SD)	30.0 (12.8)
Migraine diagnosis, n (%)	
Episodic migraine	14 (52)
Chronic migraine	13 (48)
MMDs, mean (SD)	14.8 (4.8)
NRS, mean (SD)	7.7 (1.3)
MAMI, mean (SD)	18.6 (12.5)
Caregivers (n)	27
Age, years, mean (SD)	48.4 (11.4)
Female, n (%)	8 (30)
Family relation	
Spouse	22 (82)
Son	2 (7)
Parent	2 (7)
Sibling	1 (4)

Abbreviations: MAMI, monthly acute medications intake; MMDs, monthly migraine days; NRS, Numeric Rating Scale.

Caregivers are directly involved in migraine management (i.e., during severe acute attacks or in cases of emergency access or simply for attending visits) or indirectly by supporting daily familial and socioeconomic activities.<sup>16,17</sup>

In our series, patients were relatively young with a long history of highly frequent disabling migraine. Their caregivers were peers; in 80% of cases, they were cohabitant spouses, mainly husbands (70%). This means that both patients and caregivers were strongly impacted by migraine during a very active phase of their lives, with potential consequences for family well-being, loss in productivity, and negative emotional feelings.

Recently, Tonini et al.<sup>18</sup> showed that around 25% of patients and caregivers reported difficulties in relationships and up to 35% indicated fatigue in daily activities.

Unfortunately, although they are crucial in several neurological conditions,<sup>2-5,19,20</sup> the figure of family caregivers in migraine has been considered in only a few studies so far.<sup>16,21-23</sup> The first two of these were phone-based surveys<sup>21,22</sup> focused on the impact of migraine on family members. Smith et al.<sup>21</sup> related that patients tend to cancel entertainment (39%), birthday/anniversary celebrations (31%), and leisure trips (22%) with their family, friends, or colleagues; Lipton et al.<sup>22</sup> reported that a rate of 5% of separation/divorce was due to migraine and that 12% of spouses felt they would have been better partners if they did not have headaches. In another two studies,<sup>16,23</sup> the migraine-caregiver dyad was contemporarily explored to document the relationship between migraine frequency and caregiver burden.

Our study, in line with these previous data, for the first time to our knowledge demonstrates the dynamic modification of caregivers' distress in relation to migraine burden improvement, and the amelioration of reciprocity within the patient-caregiver dyad, after galcanezumab 6-month treatment.

There is no agreement on a specific validated scale to calculate the migraine caregiver's distress. Different studies have used different questionnaires: the Family Burden Module in the CAMEO study,<sup>23</sup> the IMPACT scale,<sup>24</sup> and narrative reports.<sup>18</sup> We decided to use the RSS and the MS because they were already used in studies of chronic neurological diseases.<sup>8,25,26</sup>

Analyzing our caregivers' distress by baseline RSS total score, we observed that it was higher (20.7 [SD = 13.7]) than for diseases with permanent neurologic dysfunctions, such as multiple sclerosis (12.6 [SD = 9.5]) and Parkinson disease (14.2 [SD = 11.2]).<sup>25</sup> In a previous study on caregivers of patients with dementia, the increase in RSS score was related to a major risk of developing psychiatric disorders, and it was suggested that those with an "RSS score <23 should be monitored with an ordinary follow-up and be referred to an educational program in the community."<sup>26</sup>

In our study, galcanezumab significantly reduced caregiver RSS values and also improved the reciprocity and shared activities from the caregiver's point of view. While 6-month MS scores were similar in caregivers and patients, the caregivers' 6-month MS scores significantly improved in three domains—values, reciprocity, and shared pleasure activities—but not in love. No significant variation in the domains was observed for patients over the same interval.

TABLE 2 Changes of migraine characteristics and caregivers' distress after 6 months of galcanezumab

	Baseline	Month 6	95% CI	p-value
<b>Patients</b>				
MMDs, mean (SD)	14.8 (4.8)	4.6 (2.4)	8.4 to 12.2	<0.001
NRS, mean (SD)	7.7 (1.3)	5.3 (2.1)	1.64 to 3.48	<0.001
MAMI, mean (SD)	18.6 (12.5)	4.3 (2.4)	9.5 to 19.4	<0.001
HIT-6, mean (SD)	68 (2.8)	53.4 (9.1)	10.7 to 18.5	<0.001
MIDAS, mean (SD)	83.6 (46.7)	15.2 (13.6)	51.2 to 91.9	<0.001
<b>MS, mean (SD)</b>				
Love	3.65 (0.33)	3.61 (0.65)	-0.257 to 0.332	0.794
Shared pleasurable activities	2.92 (0.71)	3.20 (0.79)	-0.755 to 0.172	0.202
Shared values	3.00 (0.62)	3.08 (0.49)	-0.405 to 0.239	0.592
Reciprocity	3.04 (0.53)	2.94 (0.65)	-0.229 to 0.432	0.524
Total score	3.12 (0.37)	3.16 (0.57)	-0.306 to 0.224	0.750
<b>Caregivers</b>				
<b>MS, mean (SD)</b>				
Love	3.75 (0.42)	3.86 (0.23)	-0.258 to 0.035	0.130
Shared pleasurable activities	2.93 (0.76)	3.26 (0.58)	-0.613 to 0.538	0.022
Shared values	3.02 (0.91)	3.41 (0.34)	-0.733 to 0.029	0.035
Reciprocity	2.78 (0.80)	3.09 (0.62)	-0.612 to 0.095	0.035
Total score	3.04 (0.61)	3.33 (0.41)	-0.508 to 0.064	0.014
RSS, mean (SD)	20.7 (13.7)	13.7 (12.4)	0.8 to 12.2	0.027

Abbreviations: HIT-6, Headache Impact Test-6; MAMI, monthly acute medications intake; MIDAS, Migraine Disability Assessment scale; MMDs, monthly migraine days; MS, Mutuality Scale; NRS, Numeric Rating scale; RSS, relative stress scale.

This suggests that the patients' migraine improvement due to galcanezumab modified their caregivers' perception of an increase of shared activities and reciprocity, as measured by MS score improvement, in a manner different from the patients who did not experience such a perception. We hypothesized that patients, despite the clinical improvement, do not resume previously "frozen" or deleted activities early on and may need more time to realize the changes in life opportunities. Interestingly, the love domain of MS, both in patients and caregivers, remained unaltered from baseline to month 6, suggesting that the disease cannot cast doubts on deep feelings like love, as observed in caregivers of patients who have had a stroke.<sup>8</sup>

The strength of our study is that, to our knowledge, this is the first examination of the modification of caregiver distress and the improvement of mutuality between caregivers and adults affected by treatment of episodic and chronic migraine with a mAbs anti-CGRP.

The main limitation of the study is that the sample size was small. Although our data need to be confirmed with larger samples, our study suggests that after 6 months, galcanezumab is not only an effective and safe therapy for migraine but it could also have a favorable effect beyond the patients' burden, reducing also caregivers' distress and improving couples' shared activities.

An educational program for migraine caregivers should be routine in headache centers because considering the well-being of migraine caregivers could ameliorate the modality of care and treatment of patients.<sup>1,2,18</sup>

#### AUTHOR CONTRIBUTIONS

*Study concept and design:* Luisa Fofi, Claudia Altamura, Giulia Fiorentini. *Acquisition of data:* Claudia Altamura, Nicoletta Brunelli, Marilena Marcosano. *Analysis and interpretation of data:* Claudia Altamura, Luisa Fofi. *Drafting of the manuscript:* Luisa Fofi, Claudia Altamura, Fabrizio Vernieri. *Revising it for intellectual content:* Fabrizio Vernieri, Piero Barbanti. *Final approval of the completed manuscript:* Luisa Fofi, Fabrizio Vernieri.

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#### CONFLICT OF INTEREST

Luisa Fofi received travel grants, honoraria for advisory boards, speaker panels, from Novartis, Eli Lilly, and Teva. Claudia Altamura received grants and honoraria for advisory boards, speaker panels, and from Novartis and Eli Lilly. Giulia Fiorentini, Nicoletta Brunelli, and Marilena Marcosano have no conflicts of interest to declare. Piero Barbanti received travel grants, honoraria for advisory boards, speaker panels, or clinical investigation studies from Alder, Allergan,

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