Poster # P62

Long-term Improvement in Migraine Outcomes following Participation in an Employer-provided Disease Management Program

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BACKGROUND

- Migraine, a debilitating neurological disorder, affects individuals during their prime working years (age 30-50 years) and imposes a substantial personal and financial burden on the sufferers, their families, and society.[1,2] The annual costs due to migraine were estimated to range from €18 to €111 billion across Europe. Of these, 77% to 93% is estimated to be attributed to indirect costs mainly due to reduced productivity at work and absenteeism.[3,4]
- Estimates from Swiss-based studies showed that individuals with migraine lost an average of 10.2-31.9 workdays/year due to migraine, highlighting a considerable impact of migraine on both patients and their employers.[5,6]
- With an aim to raise awareness of migraine in the workplace and provide free coaching to employees and their family members living with migraine, Novartis launched the Migraine Care program using integrated digital solutions, such as telemedicine and software applications designed in collaboration with patient groups and leading experts in Headache Neurology. The program was provided as a complimentary service to all Swiss-based Novartis associates and their family members to empower them in the management of the disease and improve their quality of life.
- Earlier published data showed that a 6-month education and support program significantly reduced migraine-related disability and promoted disease management among employees.[7,8]

OBJECTIVE

- To assess the long-term impact of Migraine Care program among its participants who further completed 3 months into the program after planned assessments at 6 months.

METHODS

- The Migraine Care program is an ongoing program, which engages employees in three integrated phases: (I) an educational awareness campaign for all employees, (II) an individualised disease management program for those living with migraine, and (III) data analysis phase, which assessed the program's impact among the participants (**Figure 1**).

Figure 1. Phases of the Migraine Care program

Phase-I: Educational awareness campaign within the company
- Educate employees about migraine for a better understanding of the disease, and to create migraine-friendly work environment within the organisation
- Educational material: automated teller machine screens, info-points, migraine awareness booth, lecture with a neurologist, postcards, newsletters, brochures, manager guides, and roll-up banners

Phase-II: Individualised migraine disease management program
- After registration, eligible participants received six monthly sessions of individualised coaching on migraine management and action plans from the telemedical nurse
- Medgate: Independent telemedicine provider conducting individualised nurse-delivered telephone coaching on migraine to the eligible participants
- Migraine Buddy®: An advanced smartphone application (developed by Healint) serves as an interface through which participants interact with the nurses. All the participants provide information throughout the program in conjunction with nurses' assessment, action plan, and other educational material

Phase-III: Data analysis
- Evaluation of migraine burden and patient engagement before and after participation in the program

- Employees (aged ≥18 years) of Novartis Pharma AG, Switzerland and their family members who provided consent through the e-diary application, were eligible to participate.
- The educational awareness campaign was designated to educate all employees (independent of their migraine status) about migraine. Following the educational awareness campaign, interested participants could self-enroll into the Migraine Care program.
- After enrollment, participants received a screening call from the telemedical nurse and consultation with a medical doctor to determine if they had migraine or a high probability of having migraine (as determined by a score ≥2 on the ID-Migraine questionnaire).[9] If the participants were assessed as potentially having migraine, they were referred to a neurologist for assessment and subsequent treatment, as appropriate. If the individual had a prior confirmed diagnosis, the doctor optimised the pharmacological therapy, as appropriate.
- Eligible participants then received six monthly sessions of individualised telecoaching on migraine management and action plans from the telemedical nurse via a specially developed module on the Migraine Buddy smartphone application. The module was also used to track progress in the program and to interact with their nurses.
- During enrollment into the Migraine Care program, interested participants could provide consent to allow analysis of their data collected during the program within the Migraine Buddy app.
- The impact of the program on migraine burden and patient engagement was evaluated through a series of validated questionnaires and assessments, including Migraine Disability Assessment (MIDAS) and Patient Activation Measure (PAM).[10,11]
  - MIDAS: A brief, self-administered questionnaire (seven questions) that quantifies headache-related disability over a 3-month recall period. Higher scores represent more severe disability. MIDAS scores are categorised into 4 severity grades: Grade I = score 0 to 5 (minimal or infrequent disability), Grade II = score 6 to 10 (mild or infrequent disability), Grade III = score 11 to 20 (moderate disability), and Grade IV = 21 and over (severe disability).[10]
  - PAM: This questionnaire measures the activation of patients in managing their own health. It assesses the patient's personal involvement, knowledge of, and actions to alleviate their condition, and maintenance of changes made using a 5-point scale (disagree strongly, disagree, agree, agree strongly, and not applicable). An abbreviated version of the PAM with 10 questions (PAM 10), which is the most widely used version of the PAM, was used for this study. Patients are categorised into one of four activation levels along an empirically derived continuum (Level 1: disengaged and overwhelmed; Level 2: becoming aware and still struggling; Level 3: taking action and gaining control; Level 4: maintaining behavior and pushing further). Participants with higher levels of activation are associated with better self-management and improved health outcomes.[11]
- The results presented here focus on the impact of the program on MIDAS, PAM and responses to an exit survey which was administered at Month 9 (i.e., 3 months after program completion) to collect feedback from the study participants on the program.
- The exit questionnaire included following assessments:
  - Patient Global Impression of Change (PGIC): The PGIC scale measures the change in the patient's overall status through a 7-point rating scale from "very much improved" to "very much worse".[12]
  - A 5-point Likert scale response ("very much so" to "none") for a question related to progress towards migraine goals: "Did you make progress toward the goals you had around managing your migraine?"
  - A 5-point Likert scale response ("very much so" to "none") for "Do you feel the program has helped you better manage your migraine?"

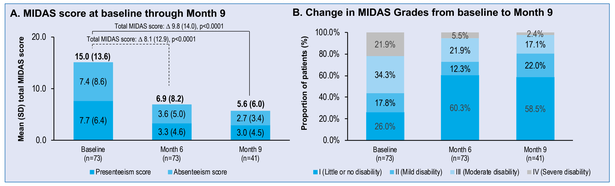
RESULTS

- Overall, 339 participants registered in the program (Jun 2018 – Oct 2019). Of these, 141 consented to the analysis of their data; 79 participants completed the 6-month program. Twenty-eight participants were still in the program and had not completed Month 6, while others dropped out either due to no further interest, lost to follow up or other health reasons. Of the 79 participants who completed 6 months program, 42 were re-evaluated at 3 months after program completion.
- Among 79 participants who completed the 6-month program, the mean (standard deviation [SD]) age was 41.5 (8.8) years, 69.6% were females, and 64.1% had a confirmed migraine diagnosis at the time of screening. About 80% of the participants were affected by migraine for more than 10 years.
- At baseline, 56.8% of these 79 participants were not being treated by a healthcare provider while 17.2% were treated by a specialist, despite 56.1% of the overall patients (n=73) having moderate to severe disability based on MIDAS data. **Table 1** presents the detailed baseline characteristics of 6-month completers.

MIDAS

- At Month 6 (n=73), the total MIDAS scores significantly improved by 54% from baseline (mean [SD] reduction: 8.1 [12.9]; p<0.0001) and at Month 9 (n=41), it further improved by 64% (mean [SD] reduction: 9.8 [14.0]; p<0.0001). The presenteeism score decreased by 57% (mean [SD] reduction: 4.4 [7.3]) at Month 6 and by 64% at Month 9 (mean [SD] reduction: 5.3 [8.0]). Similarly, the absenteeism score decreased by 51% at Month 6 (mean [SD] reduction: 3.8 [7.7]), and by 63% at Month 9 (mean [SD] reduction: 4.5 [8.2]) (**Figure 2A**). The percentage of employees with MIDAS Grade I increased, whereas those in MIDAS Grades III and IV decreased from baseline at the follow-ups (i.e., reduced disability) (**Figure 2B**).

Figure 2. Impact of Migraine Care program on (A) MIDAS scores and (B) MIDAS grades



MIDAS: Migraine Disability Assessment; SD: standard deviation

Table 1. Baseline characteristics of included participants in the program

	6-month completers (N=79)
Age, mean (SD) years	41.5 (8.8)
Gender, n (%)	
Female	55 (69.6%)
Participant status, n (%)	
Employee	78 (98.7%)
Family	1 (1.3%)
How long affected by migraine,* n (%)	
<1 year	0 (0.0%)
1-5 years	8 (10.3%)
6-10 years	8 (10.3%)
11-15 years	5 (6.4%)
16-20 years	25 (32.1%)
21+ years	32 (41.0%)
When diagnosed,* n (%)	
No diagnosis	28 (35.9%)
In the last 3 months	1 (1.3%)
3-6 months	1 (1.3%)
6-12 months	0 (0.0%)
1-2 years	7 (9.0%)
2-5 years	8 (10.3%)
5-10 years	4 (5.1%)
10+ years	29 (37.2%)
Treated by HCP, n (%)**	
No	46 (56.8%)
Yes, by physician	21 (25.9%)
Past or current treatment by a specialist	14 (17.2%)
MIDAS grades n (%)#	
Grade I (MIDAS score 0–5): Little or no disability	19 (26.0%)
Grade II (MIDAS score 6–10): Mild disability	13 (17.8%)
Grade III (MIDAS score 11–20): Moderate disability	25 (34.2%)
Grade IV (MIDAS score 21+): Severe disability	16 (21.9%)

*Two participants who completed Month 0 did not complete Month -1 assessments (screening); **Participants could provide more than one response; #N=73 for MIDAS grades (program participants who completed both baseline and 180 day MIDAS assessment)
HCP: healthcare provider; OTC: over-the-counter; SD: standard deviation

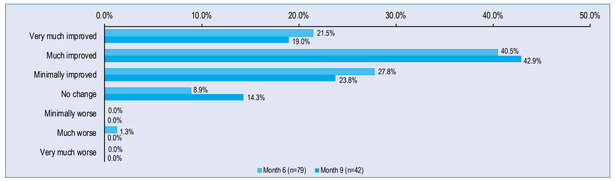
PAM

- At Month 6 (n=78), the mean (SD) PAM score significantly improved by 8% from 63.8 (10.9) to 69.6 (12.8) (mean [SD] increase: 5.8 [12.8]; p=0.003). Among those who completed the Month 9 follow-up (n=42), the mean (SD) PAM score significantly improved by 11% from 63.5 (10.7) to 71.3 (12.2) (mean [SD] increase: 7.8 [11.0]; p=0.003). At Month 6, 92.3% and Month 9, 90.5% of participants were activated (PAM levels 3 and 4), while none had poor activation (PAM level 1).

PGIC

- Approximately 90% of the participants at Month 6 (n=79) and 86% at Month 9 (n=42) reported feeling improved (under "minimally", "much", and "very much" categories) compared to baseline on the PGIC scale (**Figure 3**).

Figure 3. Impact of program on PGIC



PGIC: Patient Global Impression of Change

Progress towards migraine goals and management of migraine

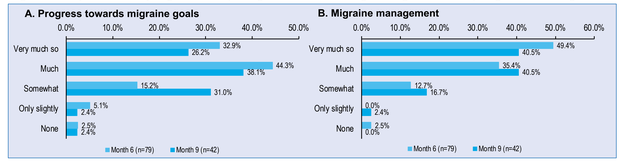
- When prompted for self-reported progress towards migraine goals and how the program helped them to better manage their migraine, 77.2% and 84.8% at Month 6 responded in favor ("much" and "very much so") of the program, respectively. Similarly, 64.3% and 81% of the participants reported similar satisfaction levels at Month 9 (**Figure 4A and 4B**).

CONCLUSIONS

- The study results demonstrate that employer-sponsored disease management program provided a better understanding of migraine and promoted methods and approaches to improved management combining medical and lifestyle options leading to significant improvements that sustained beyond the intervention supporting prolonged effectiveness of such programs.
- The systematic inclusion of such a program to corporate well-being programs would be of significant benefit to the impacted individuals, companies and ultimately societies.

RESULTS (Continued)

Figure 4. Impact of the program on A) Progress towards migraine goals and B) Migraine management



LIMITATIONS

- The major limitations of this study include non-generalisability of results, as this study was limited to Novartis employees and their family members, and absence of a control group to allow for an adequate comparison.
- In addition, dropout rates from the program may also affect the study results. The dropout rate is typical of questionnaire-based studies with no financial incentive; however, it induces a bias in favor of those most invested in the program or those with a greater awareness of migraine.

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DISCLOSURES

Leonhard Schaetz and Juanzhi Fang — Employees of Novartis and hold shares of Novartis; **Timo Rimner** — Employee of Medgate, Basel, Switzerland; **Purnima Pathak and Jelena Mueller** — Employees of Novartis; **Deepak Chandrasekhar and Lawrence Vandervoort** — Employees of Healint Pte Ltd., Singapore; **Andreas R. Gantenbein** — Received honoraria for consulting or lecturing from Allergan, Almirall, Amgen, Curatis, Eli Lilly, Medgate, Novartis, Pfizer, Roche, Streuli and Teva pharmaceuticals. He has served on advisory boards for Allergan, Almirall, Amgen, Eli Lilly, Grünenthal, Medgate, Novartis and Teva pharmaceuticals; **Peter S. Sandor** — Received honoraria from consulting or lecturing from Novartis, Biomed and Teva pharmaceuticals. He has served on advisory boards for Novartis, Eli Lilly, Teva pharmaceuticals, Roche, Biogen, Sandoz, Allergan, and Boehringer Ingelheim.

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