Improving Self-Management of Type 2 Diabetes in Overweight and Inactive Patients Through an Educational and Motivational Intervention Addressing Diet and Physical Activity: A Prospective Study in Naples, South Italy

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ABSTRACT

Introduction: Nutrition and physical activity are key elements in the prevention and management of type 2 diabetes. A community-based, multidisciplinary educational intervention aimed to improve quality of life and disease self-management in sedentary, overweight/obese type 2 diabetic patients was implemented in Naples, South Italy.

Methods: The 9-month intervention included a motivational program, a nutrition program, and an exercise program. Satisfaction, worry, and embarrassment regarding their condition, together with disease-related behaviors and propensity towards physical activity, were evaluated through a validated questionnaire before and after the intervention; health status perception was evaluated through the short-form 12 questionnaire. Changes in HbA1c level and weight were also checked.

Results: A significant improvement \( (p < 0.05) \) was registered in behaviors related to the management of hypoglycemic crisis and food choice; in nearly all the items related to living with the disease \( (p < 0.01) \); and in health status perception \( (p < 0.01) \). The adoption of healthy behavior was more common among women (OR 2.17, 95% CI 1.09, 3.02) and persons with higher educational levels (OR 1.26, 95% CI 0.83, 2.17; OR 1.54, 95% CI 0.56, 2.27). About 30% of participants did not modify their emotional status after the intervention. Although not significantly \( (p = 0.18) \), the trust of patients towards physical activity increased at the end of the study, together with their active lifestyle \( (p < 0.01) \) and with the decrease of perceived barriers \( (p < 0.01) \). A significant improvement was registered in glycemic control and weight status \( (p < 0.01) \).

Conclusions: The intervention was feasible and effective in addressing diet and physical activity among participants, giving consequent improvements in health status. Similar educational interventions including a training program for people with diabetes should be standardized and adopted by the Italian National Health System.

Keywords: Type 2 diabetes; Self-management education; Exercise; Healthy lifestyles
INTRODUCTION

Nowadays, type 2 diabetes (T2D) represents a serious global health problem. In recent decades the prevalence of T2D has increased worldwide, with values higher than 5% in Italy [1, 2]. Diabetes prevention and control may be influenced by behavioral factors such as diet and physical activity (PA). A healthful eating pattern is one of the key components of diabetes management [3]. Furthermore, in order to improve blood glycemic levels, daily PA and structured exercise sessions are recommended in individuals with T2D [4].

Lifestyle changes may be difficult to undertake, especially in older adults; therefore, self-management education and support focused on general knowledge of diabetes, adherence to therapy, lifestyle changes, and self-monitoring of blood glucose are fundamental to optimize glycemic control in order to prevent or delay acute and chronic complications and to improve quality of life for people with diabetes [5, 6]. The American Diabetes Association established the terms of Diabetes Self-Management Education (DSME), which may be briefly defined as the evidence-based process of facilitating the knowledge, skill, and ability necessary for self-care in patients with diabetes, aiming to improve their clinical outcomes, health status, and quality of life; and of Diabetes Self-Management Support (DSMS), which includes behavioral, educational, psychosocial, or clinical activities that assist the persons with diabetes in implementing and sustaining the behaviors needed to manage their condition [6].

A lot of evidence shows that educational programs addressing nutrition and training administered in the community setting for those with T2D can lead to favorable health benefits, including weight reduction, decrease of cardiovascular risk, and improved physical function, especially when these interventions include a cognitive-behavioral approach [7–14].

In Italy, the use of the group care model, which is based on a clinical-educational approach, seems to be cost-effective and successful in improving diabetes management and quality of life in patients with T2D [15–17]. However, the use of therapeutic education for these patients in clinical practice encounters difficulties mainly due to the lack of time and facilities allocated to this activity, and to the scarcity of trained operators [18].

We performed a study to verify the feasibility and efficacy of a community-based, multidisciplinary educational intervention aimed to improve quality of life and disease self-management in sedentary, overweight, or obese type 2 diabetic patients in Naples, South Italy.

METHODS

This study was part of a health promotion intervention funded by the National Center for Prevention and Control of Diseases of the Italian Ministry of Health. It aimed to evaluate possible changes in health perception and compliance to recommendations in a sample of individuals with T2D after a 9-month educational and motivational intervention. Conduct and quality of life indicators related to the disease were assessed in participants before and after the intervention, together with glycated hemoglobin (HbA1c) level and weight. The investigation was neither experimental nor controlled. Therefore, a trial registration was not provided.

Participants and Setting

During the preliminary phase of the study (3 months), physicians and diabeticians identified in their databases patients who were eligible and invited them to participate in the investigation. Eligibility criteria were age between 50 and 70 years, living in the community, diagnosis of T2D at least 1 year prior, absence of major complications of diabetes, overweight/obesity (body mass index ≥25 kg/m²) and physical inactivity (i.e., not reaching PA levels recommended by World Health Organization guidelines) [19]; limitations for PA and concomitant participation in supervised exercise programs were also considered as exclusion criteria. Individuals who decided to take part to the intervention underwent a medical evaluation to certify their
suitability for moderate and vigorous PA. All participants were informed about the purpose of the study and the use of resulting data, and signed an informed consent for being included in the intervention.

**Intervention**

The intervention lasted 9 months and included a motivational program, a nutritional program, and an exercise program. The motivational program was carried out through fortnightly group meetings guided by a psychologist with expertise on motivational interviewing for behavior change and focused on diet and PA benefits in diabetes, suggestions of home-based and outdoor training methods, analysis of barriers, and problem solving.

The nutritional program was structured in quarterly group meetings with a trained nutritionist, who discussed with patients the role of diet in diabetes control, the benefits of the Mediterranean diet, healthy food choices, and the possibility to manage their own nutrition through an adequate daily distribution of meals. Detailed information about how to prevent and manage hypoglycemia were given.

The exercise program consisted of 1-h training group sessions performed two times per week on non-consecutive days and supervised by exercise professionals with expertise in adapted physical activity. Training was tailored to the patients’ physical conditions and periodically modified on the basis of their advances. It included moderate-to-vigorous aerobic and resistance exercises. The sessions were carried out in gyms that were selected considering their availability of trained staff and adequate spaces.

All procedures followed were in accordance with the ethical standards of the responsible committee on human experimentation (institutional and national) and with the Helsinki Declaration of 1964, as revised in 2013. Informed consent was obtained from all patients for being included in the study.

**Outcomes**

Diabetes-related behaviors, beliefs, and quality of life, together with HbA1c level and weight, were assessed before \((T_0)\) and at the end \((T_1)\) of the activities in participants to evaluate the effects of the intervention.

We administrated to the participants a disease-specific questionnaire which was previously validated in another intervention granted by the National Center for Prevention and Control of Diseases of the Italian Ministry of Health (http://www.ccm-network.it/progetto.jsp?id=node/1245&idP=740). This questionnaire was composed of three parts.

The first one was aimed at evaluating how participants perceived their health status and lived with the disease; they were asked to attribute a score between 1 and 5 to their satisfaction, worry, and embarrassment level, adopting 1 as “no” and 5 as “very”.

The second part of the questionnaire included questions about behaviors that participants adopted to manage their condition; they were invited to choose one among three proposed answers.

The third part was focused on beliefs and barriers to engaging in PA; questions regarding beliefs allowed a choice among “yes”, “no”, and “I don’t know” where useful, while those regarding perceived barriers provide for a list of possible answers, allowing multiple responses.

In order to assess self-perception of health status in participants, they were asked to fill in the 12-item Short Form Health Survey (SF-12) [20]. This instrument contains eight subscales as the original 36-item questionnaire: physical functioning (two items), role limitations due to physical problems (two items), bodily pain (one item), general health perceptions (one item), vitality (one item), social functioning (one item), role limitations due to emotional problems (two items) and mental health (two items).

Questionnaires were self-administered, but an operator was always available to help respondents in case of difficulties.

**Statistical Analyses**

Health perception items, behaviors related to diabetes, and beliefs about PA were expressed as number and percentage of respondents for each proposed answer. The level of satisfaction about
the different aspects of life with the disease was expressed as modal values. Differences between the answers registered before and after the intervention were evaluated through the Chi-squared ($\chi^2$) test. Differences between mean HbA1c levels and weight measured at the two times were evaluated through Student’s paired $t$ test.

A logistic regression analysis was also carried out to identify factors associated with the probability of changing behaviors related to nutrition and PA. Age (classified in the two ranges 50–59 and 60–70 years), gender, education (categorized as primary/middle school, high school, university degree) were considered as independent variables and improvement in self-management (expressed as at least one healthy behavior adopted = 0, no healthy behavior adopted = 1) as dependent variable. Odds ratios (ORs) and related 95% confidence interval (95% CI) were reported.

A $p$ value of 0.05 was adopted as significance level. Data were analyzed with IBM SPSS version 23 for Windows (SPSS, Chicago, IL, USA).

RESULTS

Out of the 130 subjects who accepted to participate in the study, 81 (77.7%, mean age 63 ± 5.8, 60.5% male) completed the questionnaires at the start and at the end of the intervention. The overall attendance rate of these subjects was 65%. No adverse events were registered.

Table 1 shows the health-related behaviors reported by patients at the two times analyzed, with related significance levels. In general, the number of patients adopting healthier behaviors increased after the educational intervention, but only changes regarding the management of hypoglycemic crisis, the choice of products ordered at the bar, and preparations for a long walk were substantial and significant.

Table 2 reports the modal answer declared by participants at $T_0$ and $T_1$ with regard to their satisfaction, worry, and embarrassment levels related to diabetes, with corresponding $p$ values. The increasing number of patients who were satisfied or not worried/embarrassed about the specific items proposed testifies to an improved adaptation to their condition. However, the number of those who reported embarrassment related to their condition did not change between the start and end of the intervention.

Table 3 includes beliefs and barriers about PA declared by participants before and after the intervention, with corresponding $p$ values. The trust declared towards PA effects and athletic trainer role increased among participants, together with their practice of unstructured PA. No differences were registered regarding the propensity of patients to engage in PA in diabetic centers. The perception of limitations to PA decreased significantly at the end of the intervention, for both psychophysical and environmental barriers.

Table 4 shows the number and percentage of participants reporting the corresponding aspects of health status perception included in the SF-12 questionnaire before and after the intervention, with significance values related to the differences between the two times. Improvements were registered for all the items; changes concerning health perception and limitations were significant, while the last four items regarding their recent emotional status did not show significant differences.

The mean value of HbA1c blood level decreased from 6.8 ± 0.7% at $T_0$ to 6.2 ± 0.8% at $T_1$ (−0.4%, $p < 0.01$), while average weight reduced from 84.6 ± 6.3 to 73.8 ± 5.8 kg (−10.8, $p < 0.01$). Figure 1 shows corresponding quarterly variations in HbA1c and BMI mean values.

Table 5 shows the results of the logistic regression analysis applied to the improvement of diabetes self-management: female gender and higher levels of education seem to be significantly related to the adoption of at least one healthy behavior after the intervention.

DISCUSSION

This study evaluated the efficacy and feasibility of an integrated educational, motivational, and training intervention aimed at enhancing the self-management of diabetes in patients with T2D to improve their health status, health perception, and quality of life. The final purpose
Table 1  Participants’ behaviors related to diabetes at $T_0$ and $T_1$, with related $p$ values from $\chi^2$ test

| Item                                                                 | No. of respondents (%) | $T_0$ | $T_1$ | $p$ |
|----------------------------------------------------------------------|------------------------|-------|-------|-----|
| Do you practice self-monitoring of blood glucose?                    |                        |       |       |     |
| Yes, frequently                                                     | 40 (49.4)              | 40 (49.4) | 0.18 |
| Yes, sometimes                                                      | 28 (34.6)              | 35 (43.2) |     |
| No                                                                  | 13 (16)                | 6 (7.4)  |     |
| What do you do during a hypoglycemic crisis?                        |                        |       |       |     |
| I drink water with sugar                                            | 34 (42)                | 50 (61.7) | 0.04 |
| I try to rest                                                        | 20 (24.7)              | 14 (17.3) |     |
| I wait until it ends                                                | 27 (33.3)              | 17 (21)  |     |
| What do you order at the bar?                                       |                        |       |       |     |
| A fresh orange juice                                                | 51 (63)                | 65 (80.2) | 0.02 |
| An ice lolly                                                         | 10 (12.3)              | 8 (9.9)   |     |
| An ice-cream                                                        | 20 (24.7)              | 8 (9.9)   |     |
| What do you do before a long walk?                                  |                        |       |       |     |
| I put some sweets in my pocket                                      | 24 (29.6)              | 26 (32.1) | 0.01 |
| I put my medicine in my pocket                                      | 53 (65.4)              | 36 (44.4) |     |
| Nothing                                                             | 4 (4.9)                | 19 (23.4) |     |
| What do you do for the care of your eyes?                           |                        |       |       |     |
| I undergo an ophthalmology visit at least every 2 years             | 53 (65.4)              | 53 (65.4) | 0.35 |
| I undergo an examination by an optician every year                  | 26 (32.1)              | 28 (34.6) |     |
| Nothing                                                             | 2 (2.5)                | 0       |     |
| What kind of fruit do you eat?                                      |                        |       |       |     |
| Apples                                                              | 39 (48.1)              | 51 (62.9) | 0.15 |
| Seasonal fruits                                                      | 39 (48.1)              | 27 (33.3) |     |
| I don’t eat fruit                                                    | 3 (3.7)                | 3 (3.7)   |     |
| Do you control your blood pressure?                                 |                        |       |       |     |
| Yes, regularly                                                      | 64 (79)                | 67 (82.7) | 0.12 |
| Yes, sometimes                                                      | 13 (16)                | 14 (17.3) |     |
| No                                                                  | 4 (4.9)                | 0       |     |
| What do you do for physical activity?                               |                        |       |       |     |
| I go out for a walk                                                 | 54 (66.6)              | 65 (80.2) | 0.06 |
| I move around at home                                               | 24 (29.6)              | 16 (19.7) |     |
| I never engage in physical activity                                 | 3 (3.7)                | 0       |     |
was to realize a model of DSME for the community setting which could be used as a reference for the implementation of an integrated healthcare path for type 2 diabetes in Italy. The intervention was focused on the promotion of lifestyle changes among sedentary and overweight/obese patients with T2D.

Our results testify to the convenience of the implementation of a similar intervention. Beyond the physical outcomes, which showed an improved weight status and glycemic control in participants, the effects of the educational and motivational programs were expressed by behaviors, perceptions, and beliefs declared at the end of the intervention. As for behaviors related to the disease, a general improvement was registered regarding nearly all the items that were chosen as indicators of good self-management. In particular, better management of a hypoglycemic crisis, based on the rapid use of sugar instead of employing rest or drugs, was observed. With regard to this aspect, fewer hypoglycemic episodes were reported by patients at the end of the intervention (data not shown). Consequently, the level of satisfaction related to their condition increased in

| Table 2 | Participants' modal answers about their level of satisfaction, worry, and embarrassment related to diabetes at $T_0$ and $T_1$, with related $p$ values from $\chi^2$ test |
|---|---|---|
| Item | Mode (%) | $T_0$ | $T_1$ | $p$ |
| How satisfied are you about | | | | |
| Your current care | Sufficiently (62.5) | Highly (50.6) | 0.01 |
| Your diet | Sufficiently (51.9) | Highly (74.0) | 0.01 |
| Your knowledge about diabetes | Sufficiently (55.6) | Highly (49.4) | 0.01 |
| Your life | Sufficiently (51.2) | Highly (76.5) | 0.01 |
| Your aspect | Sufficiently (47.6) | Highly (92.5) | 0.01 |
| Your physical activity | Sufficiently (54.9) | Highly (83.9) | 0.01 |
| Your work | Sufficiently (48.8) | Highly (88.8) | 0.01 |
| Your free time | Sufficiently (43.9) | Highly (80.2) | 0.01 |
| Your relationships | Sufficiently (47.6) | Highly (97.5) | 0.01 |
| Your sex life | Sufficiently (53.1) | Highly (50.6) | 0.01 |
| Your sleep | Sufficiently (30.5) | Highly (75.3) | 0.01 |
| How much are you worried about | | | | |
| Your care | Not at all (73.4) | Not at all (88.9) | 0.01 |
| Death | Not at all (55.1) | Not at all (76.2) | 0.01 |
| Complication of diabetes | Not at all (27.8) | Not at all (61.5) | 0.01 |
| Influence of diabetes on your relationships | Not at all (96.2) | Not at all (100) | 0.01 |
| How much are you embarrassed about | | | | |
| Your condition | Not at all (77.7) | Not at all (77.7) | 0.85 |
| Your diet | Not at all (36.7) | Not at all (81.0) | 0.01 |
| Hypoglycemic crisis | Not at all (73.4) | Not at all (92.5) | 0.01 |
Table 3 Participants’ beliefs and behaviors related to physical activity at $T_0$ and $T_1$, with related $p$ values from $\chi^2$ test

| Item                                                   | No. of respondents (%) | $p$  |
|--------------------------------------------------------|------------------------|-----|
| Do you think that physical activity can greatly improve diabetes? |                        |     |
| Yes                  | 64 (79)                | 71 (87.6) | 0.18 |
| No                   | 15 (18.5)              | 10 (12.3) |     |
| I don’t know         | 2 (2.5)                | 0        |     |
| Do you think that the presence of an athletic trainer may be useful in the diabetes center? |                        |     |
| Yes                  | 74 (91.3)              | 81 (100)  | 0.02 |
| No                   | 1 (1.2)                | 0        |     |
| I don’t know         | 6 (7.4)                | 0        |     |
| If the diabetes center provided free physical activity programs, would you use this service? |                        |     |
| Yes                  | 81 (100)               | 81 (100)  | NA  |
| No                   | 0                      | 0        |     |
| Do you regularly engage in physical activity (in addition to the exercise proposed)? |                        |     |
| Yes                  | 55 (67.9)              | 75 (92.5) | 0.01 |
| No                   | 26 (32)                | 6 (7.4)   |     |
| What are your main barriers to engaging in regular physical activity? |                        |     |
| Physical barriers   |                        |         |
| Cardiovascular disorders | 22 (27.1)            | 11 (13.5) | 0.01 |
| Respiratory disorders | 10 (12.3)              | 7 (8.6)   |     |
| Osteoarticular disorders | 19 (23.4)            | 18 (22.2) |     |
| Excessive weight     | 13 (16)                | 10 (12.3) |     |
| Hypoglycemic crisis  | 6 (7.4)                | 5 (6.1)   |     |
| No physical barrier  | 11 (13.5)              | 30 (37.0) |     |
| Psychosocial barriers |                       |         |
| Laziness              | 41 (50.6)              | 17 (21)   | 0.01 |
| Lack of companions   | 4 (4.9)                | 3 (3.7)   |     |
| Lack of physician recommendations | 7 (8.6)            | 7 (8.6)   |     |
| Low importance attributed to physical activity | 5 (6.1)             | 2 (2.5)   |     |
| Feeling unable to exercise | 6 (7.4)            | 2 (2.5)   |     |
| No psychosocial barrier | 18 (22.2)           | 50 (61.7) |     |
participants at the end of the intervention, while worries and embarrassment regarding some specific aspects related to the disease decreased. Regarding health perception, the items related to the physical condition showed significant improvements, while those related to the emotional status improved to a lesser extent. This could be associated with the declared embarrassment regarding their condition that was reported by about 30% of the sample, and which may sub tend a psychological distress. It was reported that the incidence of some psychological disorders is higher in individuals with diabetes than in the general population, and that improvements in psychological well-being and quality of life after a specific intervention may result in better metabolic control [21, 22]. Therefore, this aspect should be considered as a key element which can influence the outcomes of educational interventions.

Table 3 continued

| Item                              | No. of respondents (%) |   |
|-----------------------------------|------------------------|---|
| Environmental barriers            |                        |   |
| Lack of time                      | 26 (32)                | 8 (9.9) | 0.01 |
| Lack of green areas               | 16 (19.7)              | 5 (6.1) |
| Lack of close gym                 | 11 (13.5)              | 8 (9.9) |
| Lack of equipment at home         | 10 (12.3)              | 3 (3.7) |
| No environmental barrier          | 18 (22.2)              | 57 (70.3) |

Table 4 Number (%) of subjects who declared SF-12 conditions at $T_0$ and $T_1$ in participants with corresponding $p$ values from $\chi^2$ test

| Item                                      | No. of respondents (%) |   |
|-------------------------------------------|------------------------|---|
| "Very good"/"excellent" health status     | 38 (46.9)              | 72 (88.8) | 0.01 |
| Moderate activity very limited by health status | 25 (30.8)              | 2 (2.5) | 0.01 |
| Very limited when climbing the stairs     | 17 (20.9)              | 4 (4.9) | 0.01 |
| In the last 4 weeks                       |                        |   |
| Performance reduced by health conditions  | 15 (18.5)              | 5 (6.2) | 0.01 |
| Activity limited by health conditions     | 20 (24.7)              | 2 (2.5) | 0.01 |
| Performance reduced by emotional status   | 35 (43.2)              | 6 (7.4) | 0.01 |
| Concentration reduced by emotional status | 25 (30.8)              | 5 (6.2) | 0.01 |
| Very limited in work by pain             | 11 (13.6)              | 2 (2.5) | 0.01 |
| Always calm and serene                   | 58 (71.6)              | 62 (76.5) | 0.59 |
| Always full of energy                    | 45 (55.5)              | 55 (67.9) | 0.14 |
| Always discouraged and sad               | 4 (4.9)                | 0 | 0.12 |
| Health/emotional status interfered with social relationships | 30 (37.0) | 18 (22.2) | 0.05 |
Furthermore, the logistic regression analysis showed higher levels of behavior changes in women and in persons with a higher educational level, as previously reported [23]. This could be considered in further studies in order to use appropriate teaching strategies for specific population categories.

Finally, we investigated the propensity of participants towards PA and exercise. Although the sample was already favorable to PA at the beginning of the study, the percentage of subjects who reported regular PA increased to 92.5% at the end of the intervention.

In a previous investigation carried out in Italian diabetes centers, the study group “Diabetes and Physical Activity” of the Italian Diabetology Society and Diabetician Association reported that 89.8% of patients interviewed trusted in PA as a therapeutic tool, while in our study this percentage was achieved only at the end of the intervention, which strengthens its usefulness. In the same study, 77% of the patients considered the role of an athletic trainer important and 94% declared their propensity to exercise in the diabetes center, while in the present investigation these percentage values were higher even before the intervention [24]. This probably testifies to an increased promotion of PA from diabeticians, which may produce an increased awareness regarding the role of PA in patients. Furthermore, the previous study reported respiratory disorders, inadequacy, and lack of time as main barriers to PA, while in our sample only the last of these represented one of the greater limitations. Anyway, after the intervention the majority of the patients did not perceive physical, psychosocial, or environmental barriers to PA.

Several studies were carried out to investigate the role of exercise in diabetes management, and they confirmed a reduction of medication use (with a consequent decrease of costs) and an improvement of clinical, metabolic, and anthropometric parameters in patients undergoing structured community programs of supervised exercise [25–34]. Most of these programs showed the opportunity to combine a multidisciplinary educational intervention with a training program in order to improve the self-management of T2D and to establish durable behavior changes [29–34]. Otherwise, it was shown that exercise represents one of the key components of educational interventions which may predict an amelioration in glycemic control and cardiovascular risk factors.
However, some other experiences reported a reduced glycemic control during the follow-up of supervised interventions, which could be attributed to the discontinuation of the educational intervention; probably recurring educational reinforcements, structured in a DSMS plan, may enhance the adoption of healthy lifestyles and should be integrated into standard diabetes care [5, 10, 11]. According to previous research, and as done in this study, similar community-based educational interventions should be coordinated with the patient’s primary care provider [36]. A recent investigation involving 10 Italian regions showed a high heterogeneity in primary care for diabetes. This leads to differences in patient satisfaction, which could affect engagement and consequently self-management [37].

Therefore, it is desirable that the Italian National Health System provide standardized T2D long-lasting paths of therapeutic education addressing healthy lifestyles and self-management of the disease in order to improve patients’ health status and quality of life. By producing a reduction of complications and medications use, this could also decrease social as well as economic costs [38].

Limitations of this study are the small size of the sample and the lack of psychological evaluation at the start of the intervention. Moreover, a comparison with patients who did not participate to the intervention would have been useful to enhance our findings. Further research should involve a higher number of patients and compare different types of educational approach with treatment as usual in order to define their efficacy in patients showing different psychological and emotional status.

CONCLUSIONS

A community-based public health intervention addressing nutrition and exercise can improve disease control and health perception in T2D patients. This pilot study provides a feasible model for DSME programs aimed at improving the health status of people with T2D, which is needed in Italy.

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Compliance with Ethics Guidelines. All procedures followed were in accordance with the ethical standards of the responsible committee on human experimentation (institutional and national) and with the Helsinki Declaration of 1964, as revised in 2013. Informed consent was obtained from all patients for being included in the study.

Data Availability. The datasets generated and/or analyzed during the current study are available from the corresponding author on reasonable request.

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