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Original Article/Research

Barriers to access to insulin pumps in Chile: A qualitative study of a high-cost technology

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ABSTRACT

Objective: To investigate the barriers to accessing advanced insulin delivery system from the experiences of patients with type 1 diabetes (T1DM), family members, and treatment teams.
Methods: A qualitative study, taking a comprehensive approach, investigated a person's experience with T1DM and receiving insulin pump treatment, emphasizing the barriers to accessing it. A case study was conducted, considering a diverse range of individuals, including young patients, adult patients, family members or caregivers, and health professionals. Twenty-nine semi-structured individual interviews provided a rich and varied perspective on the issue.
Results: According to study participants, the main barriers to access to insulin pump treatment for T1DM patients in Chile were the following: (i) Geographic barriers, (ii) Socioeconomic barriers, (iii) Administrative barriers, and (iv) Barriers from health teams. Participants also identified emerging barriers related to the insulin pump's adaptation process.
Conclusions: Despite the barriers and bottlenecks identified, an effort to fill short gaps in access to insulin pump treatment by the Chilean health system is recognized. To keep improving in equitative access to high-cost treatments in T1DM and other chronic conditions, it is imperative to consider the active and meaningful participation of patients and their families in health decision-making. This can lead to more patient-centric and effective healthcare policies and practices.

Introduction

Type 1 diabetes (T1DM) is a chronic disorder in which the pancreas produces very little or no insulin. It is a chronic disease with a significant burden of disease with complex adaptation to daily life and with a high risk of complications. This disorder has no cure, and its treatment focuses on controlling blood sugar levels with insulin, along with dietary and lifestyle adjustments to prevent complications [1]. It is estimated that approximately 422 million people in the world have been diagnosed with diabetes, of which 62 million live in countries in the Americas [2]. Of these, 9 million were diagnosed with T1DM in 2017 [2]. In the Americas, T1DM was the sixth leading cause of death in 2019, with an estimated 244,084 deaths being directly caused by this disease. Additionally, it is the second leading cause of disability-adjusted life years (DALYs) [2]. In Chile, it is estimated that around 30,000 people will be diagnosed with this condition by 2023 [3]. Thus, in recent decades, Chile has gone from having a low incidence of DM1 to a country with an intermediate incidence [4].

Optimal management of this pathology requires efficient metabolic control of blood glucose levels and strict administration of insulin to avoid hypoglycaemic or hyperglycaemic events [4]. Technologies such as continuous subcutaneous insulin infusion (CSII), continuous glucose monitoring (CGM) and the integration of both systems (SAP) improve glycaemic control [5]. The latest treatment modality is the advanced hybrid closed-loop (AHCL) and real-time continuous glucose monitoring (RT-CGM) system. These technologies allow for tighter glucose control without increasing the risk of hypoglycaemia [6]. In some cases, glucose sensors and insulin pumps are combined with a control algorithm that delivers an automated insulin delivery response. This combined system has been associated with better control of T1DM [7–10]. In May 2021,

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the WHO World Health Assembly agreed to strengthen diabetes prevention and control. Among the recommended actions, a fundamental pillar was to increase access to insulin, promoting the convergence and harmonization of regulatory requirements for this medicine [2]. Despite this, access and reimbursement policies for this type of health technology are heterogeneous worldwide [11–13].

The Chilean Health System is a mixed system with public and private participation. It is organized into three levels of care: primary, secondary specialist and tertiary hospital care. Because of their segmentation and fragmentation, health care establishments are not sufficiently coordinated with each other. The patient navigates between primary care and hospital care without receiving guidance from the system. This process lengthens patient management, duplicates services, generates competition between centres and makes the use of available resources inefficient [14]. The Chilean health system has faced a profound reform process in recent decades. It began in the 90 s and culminated in 2005 with a model that sought to provide timely care of guaranteed quality, accessible, and financial coverage for some health benefits that were prioritized [14,15]. With this, a Plan for Universal Access to Explicit Guarantees (AUGE), also known as the General Regime of Explicit Guarantees in Health (GES), began to be implemented in Chile. AUGE/GES today guarantees coverage of 87 diseases through the National Health Fund (Fonasa) and the Pension Health Institutions (ISAPRE), including T1DM [16].

The Ricarte Soto Law (LRS) was enacted in 2015, a financial protection system for high-cost diagnoses and treatments with universal coverage in Chile. It grants financial protection to all users of the health pension systems: FONASA, CAPREDENA, DIPRECA and ISAPRES, regardless of their socioeconomic situation. Covers 100 % of the value of selected high-cost medications, medical devices, or foods. For some of these health problems, it also guarantees coverage of the diagnostic confirmation exam [17]. In 2017, the LRS incorporated treatment based on insulin administration through subcutaneous insulin infusers (insulin pumps) for people with unstable and severe T1DM [18,19]. The Minimed 640 G (SAP) and 780 G (AHCL) insulin pumps are delivered through the LRS, with an automated insulin delivery system [20]. To assess if the patient is suitable for this high-cost technology, they must undergo an evaluation by a multidisciplinary team of a diabetologist or endocrine doctor, nurse, nutritionist, and psychologist. This evaluation must be carried out in a health centre authorized for this purpose. Subsequently, an independent committee of experts evaluates the case and decides whether to give the patient the insulin pump [21].

Despite all the progress made in Chile regarding access to insulin pumps for people with T1DM, the evidence also recognizes barriers that limit access [22]. Evidence suggests the high costs of the pump and its long-term monitoring as supply barriers [23–25]. Regarding demand, less access to this technology has been reported in people with a lower socioeconomic level, from ethnic groups [26,27] and with fear or discomfort with using the pump [28]. Currently, no study in Chile documents perceived barriers to insulin pump access. This study investigated the barriers to accessing advanced insulin delivery system from the experiences of patients with T1DM, family members, and treatment teams.

Methods

Study design

In 2022, the study "Type 1 Diabetes Mellitus in Young and Adult Patients in the Public and Private Health System in Chile: Unveiling the Patient Journey within the framework of the LRS" was conducted, and the general results are available [29]. This secondary sub-analysis investigated the perceived barriers to accessing the insulin pump as a high-cost technology in Chile.

This study investigated a person's experience with T1DM and receiving insulin pump treatment. It emphasized the perceived barriers that arise during the general therapeutic trajectory, especially when accessing the insulin pump [30]. We conducted a qualitative case study, a methodological design in which the researcher explores a contemporary and natural bounded system (i.e., a case) through in-depth data collection from various sources of information [31]. The study was approved by the Scientific Ethics Committee at Universidad del Desarrollo (code 2022–61).

Recruitment and selection of participants

A convenience recruitment and sampling strategy was defined [31] through (i) verbal dissemination by key actors who acted as a recruitment seed and incorporated new participants over time; (ii) dissemination through social networks, mainly Facebook Web Pages of groups of patients and relatives of patients with T1DM. Interested participants contacted the study coordinator between July and August 2022 by text or email. They were given the study information sheet, and doubts were resolved before being invited to sign the informed consent and possible interview date. Digital informed consent was applied after confirming voluntary participation in the study.

Following feasibility criteria and previous studies [32], an initial sample size of 28 to 32 participants was estimated: 4–5 young patients, 4–5 adult patients, 8–10 family members or caregivers and 12–14 health professionals. A total of 29 participants were included in the study once data saturation for the main topics had been achieved [33]. Nineteen participants resided in the capital, Santiago, while ten came ~~from~~ other regions. Among the participants, eight were patients, eight were family members, and thirteen were healthcare workers (Table 1).

Data collection

Semi-structured individual interviews were conducted online during the COVID-19 pandemic with adult and young patients with T1DM who used the insulin pump and with immediate family members and health professionals from the public and private sectors. The preferred platform was Zoom, but similar platforms, such as Meet or WhatsApp video calls, were also used depending on the participant's convenience. Data was collected between September and November 2022. A pre-established interview script consisting of 16 questions related to the therapeutic

Table 1
Study participants.

Participants	N = 29	N	%
Profile			
	Young patients	4	14 %
	Adult patients	4	14 %
	Relatives	8	28 %
	Health professionals	13	45 %
City			
	Iquique	1	3 %
	Antofagasta	1	3 %
	Viña del Mar	2	7 %
	San Felipe	2	7 %
	Santiago	19	66 %
	Talca	1	3 %
	Concepción	1	3 %
	Temuco	2	7 %
Gender			
	Male	6	21 %
	Female	23	79 %
Age			
	15–25	4	14 %
	26–35	9	31 %
	36–45	5	17 %
	46–55	7	24 %
	56–65	4	14 %
Health System			
	Public	13	45 %
	Private	16	55 %

trajectory was applied, including some about the experience of insulin pump treatment. Regarding the insulin pump dimension, open questions were considered regarding (i) AUGE/GES coverage, (ii) application to the Ricarte Soto Law, (iii) initiation of treatment, (iv) treatment and monitoring equipment, (v) general insulin pump treatment experience. Each interview lasted approximately 60 min.

Data analysis

Semi-structured interviews were transcribed verbatim, and a unique code was assigned to protect participants' confidentiality. Thematic analysis was carried out in analysis categories designed from the interview script, and emerging categories were also admitted. Some quotes selected to exemplify each category and analysis code identified were translated from the original Spanish to English and then re-translated from English to Spanish. An independent researcher reviewed the coherence and meaning of both quotes before using them for publication [34].

Ethical considerations

This study strictly adhered to the guidelines and regulations for research involving human participants, including the Declaration of Helsinki. Approval was obtained from the Ethics Committee of the Universidad del Desarrollo (#2022–61). A digital informed consent was obtained after confirming voluntary participation in the study through the encrypted platform Alchemer, ensuring the security of the information.

Results

According to study participants, the main barriers to access to insulin pump treatment for T1DM patients in Chile were the following: (i) Geographic barriers, (ii) Socioeconomic barriers, (iii) Administrative barriers, (iv) Barriers from health teams, and (v) Adaptation process barriers. These outcome categories and their principal codes are summarized in Fig. 1.

Geographic barriers

Patients and relatives perceived that regions lacked specialist doctors to guide the process of accessing the insulin pump, since all resources are concentrated mainly in the metropolitan region of the country and to a lesser extent in regional capitals. Patients perceived that they must settle for poor treatment and no expectation of accessing the insulin pump, or travel from rural areas or small cities to regional capitals to be able to apply for insulin pump delivery, which is possible only by applying to Ricarte Soto Law, process that is led by a T1DM reference center, not by any T1DM specialist. This journey entailed a significant out-of-pocket expenditure.

"…I contacted [the doctor], and she agreed to see [my son], so we travelled to Antofagasta… and indeed he was a [candidate] for the pump, and he was transferred from Iquique to Antofagasta" (Relative no 3 young patient, public system, Region II).

Professionals in healthcare teams treating people with T1DM confirmed that their workplaces, recognized as T1DM reference centres, provide treatments to an entire region. Hence, many people from different cities around the region must travel for this insulin pump treatment.

"We even see the entire region. Patients from Tal-Tal, Tocopilla, Mejillones, Calama […]". (Health professional 2, Public system, Region III).

The interviewees also recognize that once the patients access to the insulin pump, to access for the GES guarantee to receive the supplies for the insulin pump they must often attend a specialist referred by the GES, that is other than their treating doctor in a distant geographic location and have little flexibility in scheduling the time to pick up supplies. Also, this implies in many cases that members of the public system must pay out of pocket for the care of a specialist in the private sector, which generates a duplication of health care in two different coverage regimes.

"The GES gives the blood glucose strips, glucagon, and glucometer. The Ricarte Soto Law gives the pump with its cannulas and sensors. It is all fantastic because the pump and the materials are always there. However, I can only pick them up in [road name in Santiago]. Moreover, they only give it once a month" (Relative 1young patient, private system,

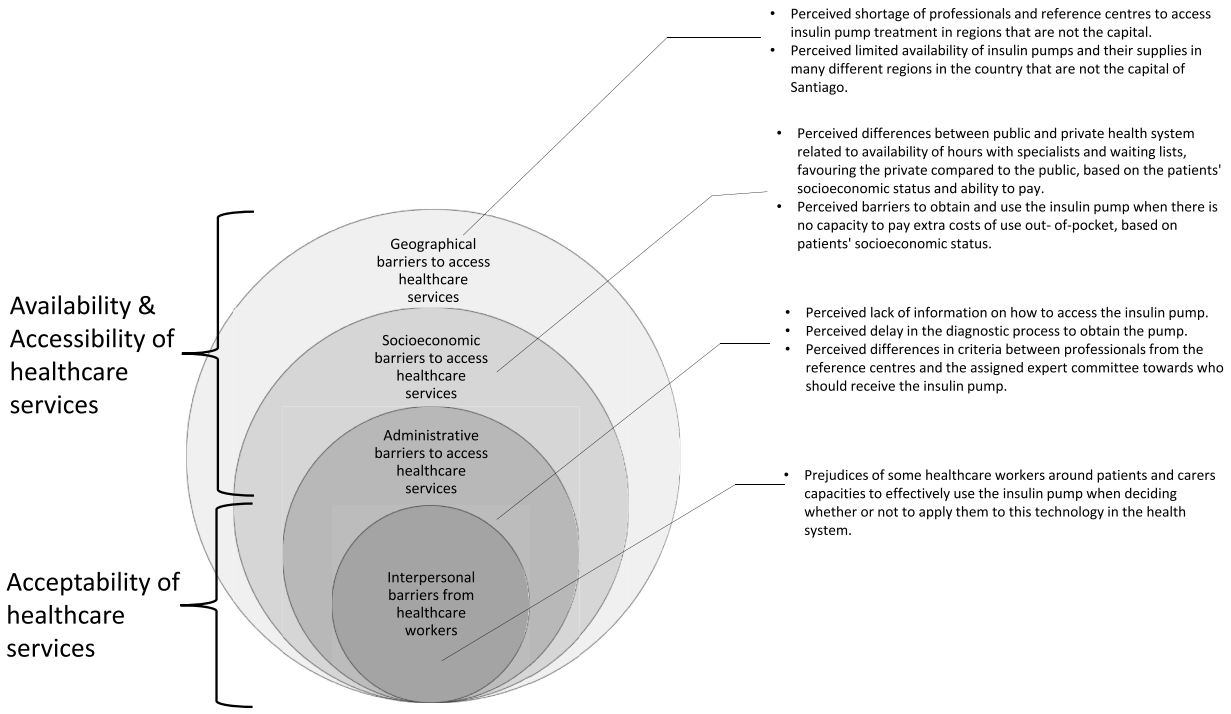

Fig. 1. Main barriers perceived by participants to accessing the insulin pump in DM1 patients in Chile.

RM).

Socioeconomic barriers

Participants perceived socioeconomic differences when accessing insulin pump treatment in the public or private systems. Some interviewed patients reported that the private system has higher out-of-pocket expenses than the public one since the process requires a series of health benefits that are not necessarily covered by the private health system

" [After the application for the insulin pump was rejected] Everything again, again to the controls at the clinic, everything private, the ISAPRE in which she is does not cover almost anything… Added to that is the round trip to Santiago, and we are waiting for the time to be available" (Relative 4 adult patient, private system, V Region).

These differences are also perceived in the monitoring of insulin pump treatment. Treatment teams perceive that in the private sector, consultations must be paid for a significant part of the total cost out of pocket, something that does not happen in the public system.

"If you are in the private system, you must pay for the doctor or the psychologist because the guarantee is not there until you enter the [GES] system. The guarantee exists once the subject becomes a subject of Law via GES" [Health Professional 8, public system, IX Region).

In turn, those interviewed commented that throughout the entire therapeutic trajectory, there are expenses associated with lifestyle adjustments since they require foods of higher nutritional quality that are more expensive.

"The patient should eat a more Mediterranean diet […] you say I am going to buy salmon and olive oil versus buying a package of noodles, and that impacts out-of-pocket spending" (Health professional 6, public system, RM).

Administrative barriers

Patients and family members report that there is misinformation about the insulin pump application process, especially in the private health system. The private system knows little about the process and offers little guidance to patients and their families.

"To be honest with you, I had heard of the Ricarte Soto Law, but I did not know that type 1 diabetes was included in this law" (Relative 2, adult patient, private system, RM).

It is perceived that in the application process for the Ricarte Soto Law, there is a long waiting time for two reasons: (i) the delay between the application and the acceptance or rejection of the device and (ii) the delay between the acceptance and receiving of the pump. It is estimated that there is an average wait between 1 and 6 months to receive a response from the independent expert committee. In turn, between acceptance and delivery of the pump, there is an additional variable waiting time between 1 and 6 months. In total, it is estimated that the application process for the Ricarte Soto Law has a waiting time of between 2 months and a year.

"It took a while, and it was a process that lasted about a year, a long process because I had to take many Lab tests, even interviews with a psychologist, I and my family had to go. Many exams" (Adult patient 4, public system, Region IX).

Once the patient receives the insulin pump, they must receive training on the use of the pump with a multidisciplinary team of nurses, psychologists, nutritionists and doctors, process supported by Ricarte Soto Law. Participants report that, on average, patients participate in between 3 and 6 training sessions.

"There were two training sessions a week, they were on Tuesdays and Thursdays (…) like 2–4 sessions (…) as it was something new my family told me that it was important for us to go, especially as I was a boy, so with those sessions we avoid having any problem with the use of the pump" (Young patient 3, public system, V Region).

Sometimes, the expert committee rejected the application made by the health teams for the insulin pump. When this happened, patients had to undergo the Lab tests again. This rejection reflects a discrepancy between the treating teams' criteria belonging to the reference centre and the independent expert committee that evaluates the application.

"I do not know… Maybe there are patients whom we consider to be candidates for the pump but who do not exactly fit the requirements required by Law to be able to apply. However, if it is a patient that we consider to be suitable and who would benefit from the use of the pump, we apply it, and sometimes it is rejected […]" (Health professional 2, private system, RM).

Participants believed that having the same professionals in the referral centres, rather than relying on an independent expert committee, would simplify the decision-making process. Finally, some administrative barriers to replacing the insulin pump are mentioned in case of failure and waiting times to continue treatment. According to what was reported by the interviewees, this happens because the eligibility criteria of the health protocol are very strict and leave many patients out, even when they have the conditions to access the benefit.

Barriers from healthcare teams

Following on from the previous idea, participants perceived judgment barriers regarding the patient's ability to take charge of their care and manage the insulin pump. It is adolescents who suffer the greatest stigmatization due to preconceived ideas of being irresponsible and incapable of committing to their care.

"When children are schoolchildren and preschoolers, parents generally do well. However, adolescence comes when the parents are exhausted, and the adolescent cannot understand […] he is not mature enough to take good care of himself…" (Health professional 4, system public, RM).

It is also mentioned that the patients' educational level and socioeconomic position play a role in deciding whether the patient is a candidate for insulin pump treatment. It is perceived that there are prejudices regarding the capabilities that people have to handle the pump in lower socioeconomic sectors or those with less education.

" […] So, there is a belief that patients who belong to lower socioeconomic strata and have a deficient level of health literacy would have more difficulties effectively using a device such as the insulin pump. So, a barrier is highly determined by the beliefs, stereotypes or prejudices of the person who prescribes the treatment" (Health professional 8, Public system, IX region).

Adaptation process barriers

Additionally, some interviewees perceive barriers to the insulin pump's adaptation process. Although they report that the pump gives them greater freedom by keeping glycosylated haemoglobin levels stable, they also say it is challenging to initially adapt to the pump, mainly due to the sound alarms it emits at night. However, after the adaptation period, the use of the insulin pump led them to improve their quality of life significantly.

"It solved my life, my life expectancy. Today I cannot be without the pump. "It is great, very good." (Adult patient 4, public system, IX Region).

Conclusions

This analysis focused on investigating the perceived barriers to obtaining and using the insulin pump, according to patients with T1DM, family members, and the healthcare workforce. Various barriers to integrating insulin pump treatment were identified, some from the users and others from the health system. Some participants emphasized geographic barriers, while others highlighted the out-of-pocket expenses associated with treatment and administrative barriers associated with waiting times. Barriers associated with individual beliefs and

perceptions from the treating teams and barriers linked to the initial adaptation to the insulin pump were also identified.

The perception of the bomb as a complex technology that requires education and monitoring is a relevant finding. This result was also recognized in some quantitative studies from other countries. This finding suggests that the need for training may be perceived as a barrier by some participants as patients may not have adequate support to adopt a new way of managing insulin [23,25.35]. On the other hand, our analysis also recognized the positive fact that the insulin pump treatment has universal coverage in Chile, which is perceived as a facilitator of accessing this high-cost technology by all study participants. This context differs from other countries where the pump must be paid out of pocket [24,25].

This unique qualitative study allowed us to know first-hand the experience of living with T1DM. Incorporating visions from various key actors (patients, family members, and health teams) contributed to a more comprehensive vision of the study reality. It is also recognized that this study initially characterized perceived barriers to accessing the insulin pump for people with T1DM. New research is required to understand these barriers and strategies that help alleviate them and benefit the health of people with T1DM and their families.

This study has strengths and limitations. It is the first study of its kind in the country and one of the few in the Latin American and Caribbean region. Its qualitative approach allowed for the exploration of themes found in the scientific literature, such as financial and administrative barriers to the pump, but also informed about new evidence related to geographical barriers, management bottlenecks and perceived mistreatment of healthcare workers, particularly towards lower income and lower education families in Chile. We recognize the exploratory and subjective nature of this study. We did not aim for causality understanding but to better comprehend how and who are able to access the insulin pump in the Chilean healthcare system. "The limited sample size allow us to focus on T1DM patients who qualify for insulin pump therapy within the framework of LRS. This serves as a starting point for studying the experiences of insulin pump treatment in Chile and the surrounding region. Future studies could further investigate specific barriers to the pump in low socioeconomic family's everyday life, as well as unique migrant and ethnic minorities that are often excluded and marginalized from multiple healthcare services. Also, quantitative studies could be developed to better explore associations between relevant variables like sociodemographic profiles, perceived barriers and effective access to the insulin pump in the country.

This novel qualitative study in Chile and Latin America suggests that despite shortcomings, the AUGE/GES universal coverage system and the Ricarte Soto Law shortened gaps in access to insulin pump treatment in Chile for people with T1DM. However, persistent perceived challenges in equitable access to the insulin pump and in the general therapeutic trajectory deserve more attention and action. These findings can serve as a reference for other countries in the region, where there may be partial or total coverage of access to insulin pump treatment. The study reflects that it is imperative to consider the participation of patients and their families in health decision-making, given that they are the ones who, from their own experience, can propose solutions and combine criteria to promote more equitable access to this technology in Chile and the region.

The benefits of insulin pump treatment are well-documented, but there are significant barriers to accessing this treatment that require urgent attention. The findings of this study can provide guidance for other countries in the region by understanding the experiences of patients with type 1 diabetes who navigate through different health systems with varying coverage for insulin pump treatment. This understanding can lead to structural changes that significantly improve the health-related quality of life for individuals with this condition.

The study's findings are significant as they reveal multiple perceived barriers to accessing the type 1 diabetes therapeutic trajectory and trying to obtain an insulin pump in Chile. By considering the experiences of patients, family members, and health professionals, it provides a comprehensive understanding of the challenges faced in the country by those living with this condition. This unprecedented study in Latin America and Chile sheds light on aspects of insulin pump treatment beyond its impact on glycosylated haemoglobin levels, demonstrating the structural difficulties faced by users in both the public and private health systems.

Ethical approval

This study received approval from the Scientific Ethics Committee at Universidad del Desarrollo (#2022–61).

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The following information is required for submission. Please note that failure to respond to these questions/statements will mean your submission will be returned. If you have nothing to declare in any of these categories then this should be stated.

Please state any conflicts of interest

A conflicting interest exists when professional judgement concerning a primary interest (such as patient's welfare or the validity of research) may be influenced by a secondary interest (such as financial gain or personal rivalry). It may arise for the authors when they have financial interest that may influence their interpretation of their results or those of others. Examples of potential conflicts of interest include employment, consultancies, stock ownership, honoraria, paid expert testimony, patent applications/registrations, and grants or other funding.

Please state any sources of funding for your research

All sources of funding should be declared as an acknowledgement at the end of the text. Authors should declare the role of study sponsors, if any, in the collection, analysis and interpretation of data; in the writing of the manuscript; and in the decision to submit the manuscript for publication. If the study sponsors had no such involvement, the authors should so state.

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Author contribution

Please specify the contribution of each author to the paper, e.g. study design, data collections, data analysis, writing, others, who have contributed in other ways should be listed as contributors.; BC, involved in the study design, data collections, data analysis, writing, editing, final revision of the manuscript.; AO, involved in the study design, data collections, data analysis, writing, editing, final revision of the manuscript.; PM, involved in the study design, data collections, data analysis, writing, editing, final revision of the manuscript.; DP, involved in the study design, data collections, data analysis, writing, editing, final revision of the manuscript.

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