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Research Article

No Clue… No Signs… Unpredictable and Bizarre: The Burden of Impaired Awareness of Hypoglycemia Among Patients on Hemodialysis—Findings of a Sequential Explanatory Mixed-Methods Study from South India

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Abstract
Impaired awareness of hypoglycemia (IAH) refers to the failure to sense or perceive a significant decline in blood glucose levels. This explanatory sequential mixed-method study aimed to determine the prevalence of IAH among patients undergoing hemodialysis and to explore the experiences of affected patients and their significant others. In the quantitative phase, IAH was assessed using Clark's questionnaire in 86 hemodialysis patients, followed by an in-depth qualitative phase involving interviews with 16 participants. Quantitative data were analyzed using descriptive statistics and tests of association, while qualitative data were examined through thematic analysis. The findings indicated that a Clark's score of ≥4, suggestive of IAH, yielded a mean score of 5.01 (±1.2), with 28.7% (±2.7) of participants experiencing severe IAH, and 40.4% reporting fear of hypoglycemia. Qualitative analysis revealed three main themes: awareness matters a lot, experiences of IAH and its impact on daily life, and solutions and strategies to address IAH. Overall, the results demonstrate a notably high prevalence of impaired awareness of hypoglycemia in the hemodialysis population, highlighting the importance of identifying IAH levels to support healthcare professionals in developing comprehensive and individualized clinical strategies for this high-risk group

Keywords: impaired awareness of hypoglycemia, hemodialysis, mixed-methods, clark's score

Introduction

Hypoglycemia is one of the most common clinical consequences in the spectrum of diabetes mellitus and its nature and presentation may vary in the context of chronic comorbidities (McCoy et al., 2020). A constellation of characteristic pathological changes in chronic kidney disease make the patients vulnerable to have varying degrees of hypoglycemia (Moen et al., 2009) .

Hypoglycemia is the fall in the plasma glucose level <70 mg/dL. Patients may manifest dizziness, fatigue, palpitations, sweating, headaches, nausea and numbness during hypoglycemia owing to the sympathetic activation. It can cause detrimental clinical consequences if not treated in time (Shafiee et al., 2012).

Background

The estimated prevalence of hypoglycemia among Indian type 2 diabetic patients was 57.44% and reported rate of severe hypoglycemia was 10.7% (Samya et al., 2019). Hypoglycemia has a direct relation with the number of hospitalizations, increased healthcare costs and poor quality of life (Williams et al., 2011). Impaired awareness of hypoglycemia (IAH) is the failure to sense or perceive a significant fall in the blood glucose levels (Elliott & Heller, 2011). The obvious

autonomic features are the classic clinical manifestation of hypoglycemia and it enables the patients to adopt precautionary measures to avoid lethal low glucose levels. Though the cause of IAH is multifactorial, it is presumed to occur due to the diminished counter-regulatory mechanisms in hypoglycemia out of chronic exposure (Martín-Timón, 2015). The Pedersen-Bjergaard group was the first who coin this concept and used the term "impaired awareness of hypoglycemia" – which describes the awareness of hypoglycemia as a continuum between totally intact awareness (aware) and impaired awareness (unaware) (Pedersen-bjergaard et al., 2007). The measurement of IAH is primarily through self-reported questionnaires, and the most common tools are the Clarke and Gold questionnaires (Ang et al., 2023).

It is understood that glucose metabolism is altered in end-stage kidney disease and it worsens in the scenario of haemodialysis (HD) due to the rapid fluid shifts, electrolyte derangements and malnutrition (Hayashi et al., 2021) (Sahathevan et al., 2020). These subsequent glycemic disarrays pose frequent glucose fluctuations and eventual fatal hypoglycemic spells among this population. Research studies are limited to substantiate the role of long-term diabetes mellitus or uremia as an independent predictor for IAH. A recent study from the UK has revealed that 23.2% of the study subjects with diabetes on hemodialysis had IAH and patients with a history of severe hypoglycemia episodes were found to be more prone to IAH (Habte-Asres et al., 2024). A large population registry-based Asian study has found diabetic end-stage kidney disease patients with higher adapted Diabetes Complications Severity Index (aDCSI) scores were associated with severe hypoglycemia (Chu et al., 2017). The reasons for the notable increase in the mortality rate among the HD population also need to be analyzed in this regard (Hayashino et al., 2007).

Many studies have investigated IAH in type 1 and type 2 diabetic population. Studies among diabetic patients revealed that IAH is correlated positively with the number of hypoglycemic episodes (Lin et al., 2020). A systematic review has revealed the pooled prevalence of IAH in type 2 DM was 23.2% (95% CI: 18.4%–29.3%) with the Clarke questionnaire (Yu et al., 2023). There is an absolute dearth of literature on IAH among hemodialysis patients except for a very recent study by Habte et al (Habte-Asres et al., 2024). If this phenomenon of dampened awareness exists across the dialysis population irrespective of diabetes status has not yet been evaluated and in-depth information on the patient experience was also lacking. Hence our first aim was to quantify the prevalence of IAH in the haemodialysis population and subsequently explore the experiences of patients and significant others through qualitative in-depth interviews.

Research Questions

1. What is the prevalence of IAH in the haemodialysis population?
2. How do patients undergoing haemodialysis experience and perceive the impact of impaired awareness of hypoglycemia?

Method

The study used a mixed-methods sequential explanatory design. This design involves collecting and analyzing the numerical data in the initial quantitative part and then recreating the construct through a qualitative part to elucidate it much better ("QUAN → qual") (Creswell, 2014). A cross-sectional design was used in the first phase and a phenomenological approach was used in the second phase. We chose a *sequential nested sampling design* which involves purposive

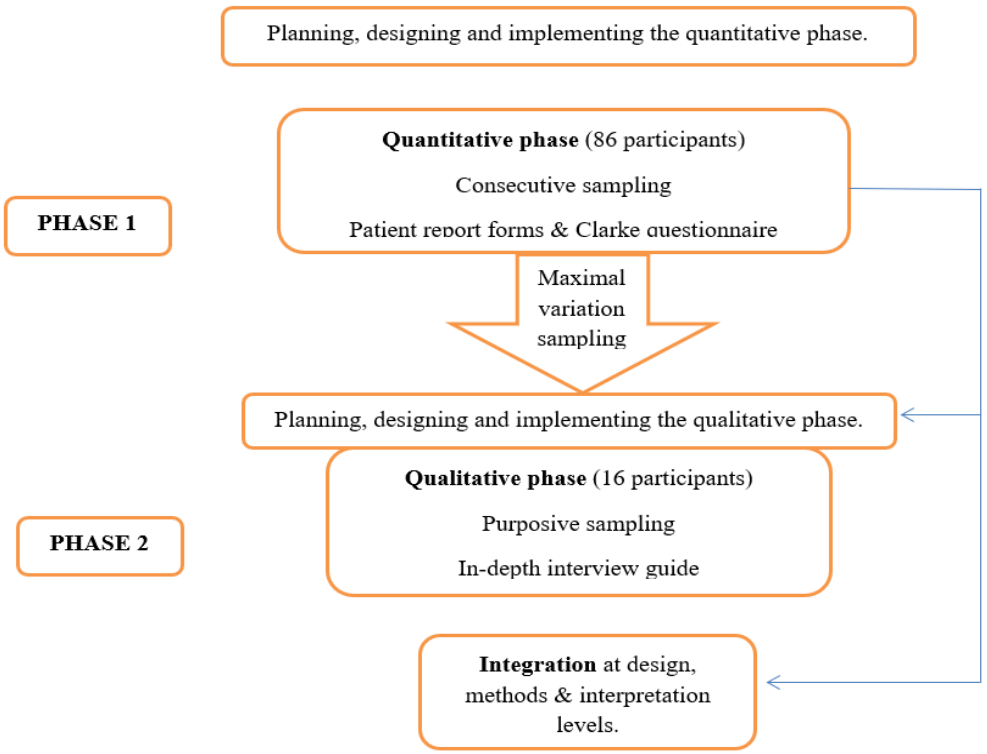
selection of samples from the quantitative phase to the qualitative phase (Onwuegbuzie & Collins, 2007). We followed a thematic analysis (TA) scheme to identify the codes, and domains and to derive the themes (Kiger & Varpio, 2020). We have reported this study using the Good Reporting of a Mixed Methods Study (GRAMMS) checklist (O'cathain et al., 2008).

This was a single-centre study encompassing all the patients undergoing maintenance hemodialysis. We conducted the study at a public sector medical college in the southernmost state of India. The centre has a full-fledged hemodialysis unit working in 3 shifts. Patients on maintenance hemodialysis were our study population. In the initial quantitative phase, we consecutively recruited all the eligible patients who met the inclusion criteria (adults undergoing hemodialysis for a minimum of 6 months, ready to give consent and able to read and write Malayalam – the official language of Kerala) at the maintenance hemodialysis unit of the centre. Patient report forms - socio-demographic-clinical data sheet and the Clarke questionnaire - were used to collect the data.

In the succeeding qualitative segment, in-depth interviews were conducted among representative candidates purposively selected from the first phase. To enhance the construct's gravity and magnitude, family members and healthcare personnel also were chosen purposively to explore their perspectives. We believe that this will yield rich data on the phenomenon of interest. We adopted a maximal variation sampling in the qualitative phase to ensure representation from varying clinical backgrounds. One of the researchers have approached the patients to invite them to the study after a thorough explanation. Written informed consent was obtained and patient information sheets were also given. Enrolment continued until saturation was attained. The methodological sequence is depicted in Figure 1. The semi-structured interview guide was prepared to elicit perspectives on the experiences of patients on IAH.

Figure 1

Methodological Sequence – Flow Chart



Data collection

Quantitative phase: The measures used in the quantitative phase were Patient report forms - socio-demographic-clinical data sheet and the Clarke questionnaire. In this phase, data was collected with the Patient report forms—the socio-demographic-clinical data sheet and the Clarke questionnaire. The socio-demographic-clinical data sheet was prepared in consultation with the experts and literature review by the investigators to collect the basic demographic (age, gender, education, occupation) and clinical details (CKD and MHD duration, comorbidities, HbA1c). Clarke score is a standardized scoring system to assess the degree of impaired awareness of hypoglycemia (IAH) which was developed and the properties were evaluated by the working group of Prof William Clarke, University of Virginia, USA. It was translated into vernacular language and found culturally appropriate and feasible in our community setting. The Clarke score consists of 8 items, encompassing different aspects of hypoglycemia. A score ≥4 suggests impaired awareness of hypoglycemia (IAH) (Clarke et al., 1995).

The eligible prospective participants were explained in detail about the study, both phases, the pattern of involvement and engagement in the qualitative phase and its process. We have taken written informed consent from each participant and they were ensured of the voluntariness, anonymity and confidentiality involved in the study. From eligible patients, the data were collected through face-to-face interviews. Both the tools were administered at the waiting lounge of the nephrology department after ensuring their comfort and it took around 15 – 20 minutes. A few patients who were not comfortable initially were consented during the later visit.

Qualitative phase: Based on the findings of the first segment, interview questions were prepared and the candidates for the qualitative phase were selected purposively, i.e. patients from the first phase (with varying levels of IAH, with varying clinical history and socioeconomic background), family members and health care team members. Separate interview guides were prepared for the three groups in a subjective frame of reference in consultation with the subject experts and in line with the literature. After piloting, necessary modifications were made and the semi-structured interview format was finalized. The interview guide consists of a broad question at first (Tell me about your hypoglycemic experiences; whether you had situations where you haven't experienced any typical symptoms?) then a few open-ended questions (Can you share an experience with us? How does it affect your daily life? How do you manage it?). Appropriate probes were added wherever necessary (Please explain more or can you cite an example). The health team members were asked mostly about the strategies to address the issue. In-depth interviews with patients and relatives were conducted in the vernacular language.

We have approached the patients to invite them to the study after a thorough explanation. At the outset, we ensured a comfortable environment for the participants. The purposes of the study and the participant's rights were elucidated and written informed consent was obtained from all the interviewees. The concept of IAH was also explained and emphasized so as not to mix it up with hypoglycemia. After ensuring the confidentiality and anonymity of their personal information, permission was obtained for audio recording. The whole process was flexible but streamlined in order to finish the interview smoothly and to adhere to the study's objectives. Each interview lasted around 40 to 55 minutes (median 45 minutes). All the interviews were audio recorded, and interview notes were also taken. This allowed for capturing nonverbal cues and gestures that would otherwise be missed in the recording. All the interviews were conducted in the patient debriefing room in the nephrology department near the HD unit. Enrolment

continued until saturation was attained. The research team has discussed on data saturation and it was obtained with 16 participants.

Data analysis

Quantitative data was analyzed using IBM SPSS software. Descriptive statistics were done to summarize the socio-personal and clinical characteristics of participants. A statistical significance level of $p < .05$ was accepted as significant.

Data analysis in the qualitative phase was an iterative and interpretive process. We used thematic analysis for data interpretation and transcripts were made out of the recorded data which was later translated into English. We read and re-read the transcripts several times to get familiarized with the data. Participants were given numbers to ensure anonymity. We generated initial codes by going back and forth through the data. Some of the initial codes were later replaced by other codes, relabeled, or removed and then collated and finally organized all the relevant codes under the proposed subdomains. Further similar codes were grouped under major themes and the reports supporting the possible themes were assembled to generate subthemes. Finally, three themes were derived and were subjected to peer and expert review. The vetted themes were again revised to ensure that the themes exactly echoed the respondents.

Trustworthiness

To ensure the trustworthiness of the data, Lincoln and Guba have proposed four important criteria, which are credibility, transferability, dependability, and confirmability (21). All the researchers possess previous experience in qualitative research. Two are nurse researchers and one has expertise in nephrology and diabetes clinical research. We read all the transcripts individually and coded them. Then codes were compared, finalized, and categorized, themes were derived both inductively and deductively in agreement with each other. Expert consultation was also sought. The researchers and participants were not related in any way.

Results

During our period of data collection, 116 patients have undergone maintenance hemodialysis at the centre. Of them, 86 patients were eligible for the study and they had a mean age of 56.5 years. The majority were males (72.5% vs. 27.9 %), 61.6 % were diabetic and of which 31.39% were on insulin. Among them, 28.7% (± 5.7) of participants experienced IAH. The mean score of IAH was 5.01(±1.2) according to Clarke's score and the mean HbA1c was 5.8 (± 1.64). Among the participants, 40.69 % had a fear of hypoglycemia. Only 3.2 % of the patients were performing regular self-monitoring of glucose at home. The mean duration of CKD was 4.8 yrs. Hospitalizations associated with hypoglycemic episodes in the last 3 months were reported by 26.74% and 62.34 % of the participants reported varying degrees of related nocturnal episodes. (Table 1).

In the next qualitative segment, data were collected from 16 participants (patients -8, family members – 4, health team members – 4). The age of patients ranged from 43–76 years with a mean age of 52.75. Both diabetic and non-diabetic patients were included (4/4) with a mean dialysis duration of 4.25 (± 1.74) years. Their mean IAH score was 6.

Table 1

Socio Demographic and Clinical Characteristics of Participants in the quantitative phase (N= 86)

S No.	Variable		Mean (SD)
1.	Age in years		56.5 (±13.4)
2.	Duration of CKD		4.72 ± 2.13
3.	HbA1c		5.77 ± 1.64
4.	Hemoglobin (gm./dl)		8.78 ± 0.85
5.	BMI (Kg/M^2)		21.15 ± 2.06
6.	Duration of dialysis (in years)		2.00 ± 0.62
	Variable	**Frequency**	**Percentage (%)**
7.	Male / Female	62/24	72.% / 27.9 %
8.	Diabetic status Yes	53	61.6 %
9.	On Insulin Yes	27	31.39%
10.	- Impaired awareness of Hypoglycemia	24	28.7.%
	-Undetermined	18	20.93%
	-Normal	44	51.16%
11	Fear of hypoglycemia	35	40.69%
12.	Regular self-monitoring of glucose	4	3.2 %
13.	Hospitalizations associated with hypoglycemia (last month)	22	26.74%
14.	Nocturnal hypoglycemic episodes.(last month)	31	62.34 %

Going back and forth through the data, the researchers could identify and highlight the trend or pattern by scribbling and colour coding. Some of the initial codes were later replaced by other codes, relabeled, or removed altogether. From the relevant code group, patterns of meaning in line with the objectives were examined for themes. Three themes were evolved; Awareness; matters a lot; Experiences on IAH, Impact on daily life, Solutions and strategies to address impaired awareness of hypoglycemia. Themes and the corresponding verbatim are following (Please refer to the code cloud and Hierarchical Model of Themes and Categories appended – figure 2).

Figure 2

Mind Map Showing The Codes, Minor Themes, and Major Themes.

Theme 1: Awareness; matters a lot - Experiences on impaired awareness of hypoglycemia

Participants reported a profoundly low blood glucose level which is devoid of any clinical features and that eventually produce a substantial degree of confusion and bewilderment among them and their families.

> Nowadays, I have low energy and am extremely weak at times. Not able to predict the spell or the trend. Previously, I have no issues with blood sugar, but it troubles me a lot these days. (Male, CKDu, 37 yrs. on MHD for the last 3 yrs. IAH- Undetermined).

> This is a new experience.... completely a bizarre one. For the last 23 years... I was diabetic. Used to get hypos in between...but it was quite different... part of life like.... used to have some shivering.... thirst or fatigue..... then I could sense that..... it was a familiar matter in the family also. Even my grandchildren used to offer candy for me... (smiles...) (72 yrs. Male patient, undergoing HD for the last 5 yrs. IAH - Severe).

Conversations revealed that fear and anxiety about nighttime events pose serious issues. Both patients and relatives were highly concerned and vigilant about these nocturnal reactions.

> This nocturnal stuff…. the worst of its kind. This is a horrifying feeling that dreads me even in the daytime. Nights are like a 'yugam' (quite a long period) for me. (Patient, female, 52 yrs. Undergoing HD for the last 4 years. IAH - Severe)

Each incident earmarks a long-lasting bearing on patients and caregivers. 'Fear of hypoglycemia' was a common feeling. During the conversation, the researcher could feel the intensity of those awful experiences - both patient and family members were pondering over. Few patients had injuries and burns during IAH episodes. Most of the reverberated words were 'unpredicted and asymptomatic'.

> The thoughts themselves numb me…that night..... while going to the washroom, he fell and had an injury to the head.....since then.....I am scared of nights.....every night... (Spouse, Female, 46 yrs.)

> No clue.....no signals.....nothing. Unpredictable. We used to end up in troubles..... a series of troubles..... one after the other. Once, I handed over a glass of hot tea to him..... he was talking to me.....within no time, I noticed that he was not responding.... a sort of 'standstill'....by the time the cup fell and had some mild burns. These are much distressing. (Spouse, Female, 48 yrs.)

The complete loss of awareness of the incident makes the patients frustrated and upset. In the scenario mentioned above, the counterpart reported a complete loss of awareness of that incident.

> I could remember even our chit-chat before that.... but later, when she narrated the whole story.... I realized my inability to recollect the interim events. It's extremely shocking..... (Male Patient, Diabetic, 54 yrs. undergoing HD for the last 7 yrs. IAH – severe).

Often, they found this as they could not manage or as being beyond their control, and it made their struggles much harder. People who are rigorously following the instructions and blood checks also felt it was a bit difficult to crack the hypos. This creates frustration and puts many of the participants in despair. They articulated the same with varying levels of intensity. One of the participants expressed concern about the extra caution and vigilance his partner exercised throughout her life to take care of him.

> You know..... she sleeps with eyes open.....(wry smile). (Patient, Male, 72 yrs. IAH – Severe, On MHD for 5 yrs. About his wife).

The blues accompanying this clinical entity and its intricacies were nearly universal among the group. Few patients had seizure episodes.

> Still remember that night...I just woke up suddenly....and he was making some incoherent sounds. There was froth from the mouth.... I was frozen.... a few seconds later, he was like a wooden piece. No response.....I screamed like anything. Nobody to call at midnight...what to do? Since then... I lost my sleep (sighs...). (Spouse, Female, 54 yrs.).

Sleep disturbances, marked anorexia, extreme fatigue and memory disturbances were the common health problems reported among patients with severe IAH. Few participants have shared their anxiety and fear about the imminent death. Falls and injuries constitute another significant issue.

> I couldn't sleep….. Sleepless nights….. you know…now, my earnest desire is to sleep madly…. fed up with these long night hours… (67 yr. old male patient on MHD for 6 yrs. IAH - severe)

> You can't imagine the degree of weariness. It's....you know... the extreme… I can't remember anything but after that...I am like a rag piece …no strength…cannot do anything…...just lying in bed…... (Female Patient, 63 yrs. Undergoing HD for the last 3 years. IAH - Severe)

> The most troubling thing...you know.....all of a sudden we hear... (he/she) is no more...one fine morning.... that fear of imminent death. ((Female Patient, Diabetic, 54 yrs. undergoing HD for the last 2 years. IAH - undetermined).

Theme 2: Impact on daily life

On probing, the participants were vocal about the direct and indirect burden posed by these unidentifiable hypoglycemic attacks. Elderly couples with no fixed income, presenting with multiple comorbidities were a universal entity, and they shared more or less similar feelings on this.

> Frequent hospitalization is a big issue..... last month also... got admitted to hospital twice. Each time...it costs a lot.... auto-rickshaw charge, hospital charge, medicine, food...nobody to help... and so on.... not able to go to work also..... (Patient, Male, 67 yrs. MHD for 6 yrs.)

Odd time happenings, transportation and unforeseen hospitalization are the typical life patterns for most patients. A mode of vicious circle which is going on and on which produces a substantial financial burden to the family.

> I don't know how to manage all these expenses. To be frank.... Somehow managing the dialysis-related and other routine expenses. These unexpected events worsen our struggles. You know..... troubling others at odd times.....running for a vehicle, money, assistance.....for me.... these all are really bothersome.....(Spouse, female - 54 yrs.)

Patients reported the consequences of this unpredictable event on their social lives and portrayed how they changed their lives.

> I am the only breadwinner in my family. I used to go for painting work on non-dialysis days. Earlier, I was ok. I had good company of friends. I used to go to films and festivals...dialysis was just a part of life.... that's all... But nowadays, I have low energy and feel extremely weak at times. Recently started this 'sugar' problems too.....(Male, 47 yrs. on MHD for the last 4 yrs.).

Financial constraints were the most projected concern owing to the loss of productive work days. A young man commented on the loss of productive days because of frequent hospitalizations.

> You know...it affects my work too.....I had sudden attacks during work.... felt embarrassed in front of my fellowmen. So now, once in a while, only I go to work. No income on dialysis days. So two days per week.....gone. On the top now this also...family income... (sighs...) ...in fact, in a pathetic stage. (non-diabetic 47 yrs. Coolie worker on MHD for the last 4 yrs. IAH - undetermined).

Being the recipient of an obligatory treatment service (hemodialysis), here just to sustain life itself is a bit extravagant, as one of the family members pointed out. So, the troubles of IAH pose an added burden to the dialysis-related stress.

> I don't know how the day-to-day affairs are going on.....working in the church school as cleaning staff. Local people used to help...you know...just because of the Karunya scheme (insurance

> programme) I am here.....to add my suffering, this sudden collapse and issues.....last time it was during meal preparation, luckily I didn't get burns. (Patient, Female, single mother, 39 yrs. MHD for the last 3 years.)

Theme 3: Solutions and strategies to address impaired awareness of hypoglycemia

Patients, family members and the health team members have opined about the feasible solutions to tackle the issue of IAH. The importance of family support and health education were highlighted.

> Yes...we need a regular structured patient education system. We used to insist on bringing interim snacks, drinks, and the importance of diet everything. But the fact is that when it comes to their routine...they may find it difficult across all hurdles. But few are doing it well (Dialysis Nurse).

> I think one major issue in communication is due to the lack of consistency of the caregiver- especially with female patients. We instruct many things with one person...then the next time it may be somebody else.... so missing that continuity in care.... that's a real issue. - Dialysis nurse.

> We both are very particular about that. My daughters are also very keen on insulin doses and diet. They chart everything ...but at times it may crack.... still manageable. (52 yrs. Male non–diabetic Patient, on MHD for the last 4 yrs.)

> It's a terrific issue (IAH spells), I know. So wherever we go, I used to keep some sweet stuff in my bag. And we are very much keen about the warning signs to prevent the attack. Luckily no grave events so far (Spouse, female, 48 yrs.).

Few of the participants were finding their ways to cope with this. A 58 yr. old diabetic lady participant with severe IAH shared her perceptions in terms of her jovial associations with healthcare personnel and echoed the value she places on the support in the management of IAH.

> Here, nurses are very friendly.....good in practical solutions also. Used to listen to them...then learn from my own experiences...too. I think I could better manage this with food. I used to eat very well.....rich breakfast, snacks, you know...liberally...(laughs).....just trying to balance...that's life. Isn't it? (Patient, Male, 67 yrs. MHD for 6 yrs. IAH - undetermined)

> I used to watch health-related programmes on television and YouTube. Interact with other patients, discuss with my family members.... etc. These all help me to know the general do's and don'ts. (Female patient, 54 yrs. Attending MHD for the last 6 years. Undetermined IAH)

The need for a person-centered approach was highlighted in the interviews with health team members. As glycemic management in the dialysis population is a sensitive matter it requires a holistic person-centered approach.

> A 'one size fits all' approach is not at all suitable.... a tailored method may be much better.... have to go a long way in this regard. - Nephrology resident.

This dearth of knowledge and understanding creates problems in glycemic management also, as one of the nephrology residents mentioned,

> Yes..... exactly...diabetic patients are conditioned to manage this hyperglycemia as they were doing in the past...but the current pathological changes they may not know.....definitely.....patient education matters a lot....

> Lack of awareness of the disease-related changes cause much confusion and doubt among patients and relatives. Many times patients ask 'I am not diabetic.... then why do you check my sugar?' This is a common scenario (Dialysis Nurse).

Patients and family members were probed about the awareness and utilization of regular blood sugar monitoring, such as self-monitoring of blood glucose (SMBG). Most of them were aware of the SMBG, but only a small number of patients were practicing the same.

> Ya...I have one (glucometer).....a few months back bought...was using it regularly. but now it's not using...because those strips are very costly. (Patient, Male, 72 yrs. MHD for 7 yrs.)

Few patients have revealed how they are anticipating the spells and making self-adjustments of insulin dosage. Patients and family, found it very useful for them.

> Previously he had very high sugar levels, but in the last few months, it's very low and he used to get these kind of bouts. Initially, we didn't know what to do...in fact.... but over the time...I could manage somehow. By adjusting insulin dose and tracking the very first changes...I don't know how? May be some intuitions...(laughs) but the frequency of events has come down. so it's just handling as it is...(Spouse, female, 48 yrs. performing regular SMBG).

Data integration:

This study followed the three-level integration process conceptualized by Creswell and Plano Clark, which occurs at three levels, viz. design, method and interpretation levels (Fetters et al., 2013). Integration at the design level occurred at the study's emergence stage, whereby the type of design employed as explanatory sequential. Integration at the methods level attained through the *connecting and merging* approaches, which combines the quantitative data and qualitative data for analysis and comparison. A mixed method matrix facilitates integration at the reporting and interpretation level (Younas et al., 2020).

Discussion, Conclusion and Recommendation

This study aimed to detect the prevalence of IAH among patients on regular hemodialysis and to explore their experiences through a sequential explanatory mixed method design. The burden of hypoglycemia among dialysis population is well studied but literature on the phenomenon of IAH in hemodialysis is scarce (Jung et al., 2010). The lack of warning signs during low glycemia puts patients in varying levels of difficulties troubling all aspects of their life. Our study findings revealed that a significant proportion of patients were experiencing IAH in their daily life. The qualitative interview transcripts were analyzed and deducted into three themes - Awareness; matters a lot; Experiences on IAH, Impact on daily life, Solutions and strategies to address impaired awareness of hypoglycemia.

Present study found that the prevalence of IAH was 28.7% which is slightly high when compared to the study by Habte et al in diabetic dialysis patients (23.2%) (9). Variances in ethnicity and BMI (21.15 ± 2.06 vs. 30.4 ±6.8) may be viewed in this regard. The interviews revealed fear of hypoglycemia as a rampant issue and this is supported by our quantitative finding (40.4%). Findings from the literature also corroborate this (9). Patients and family members generally expressed the feelings of anxiety, fear of fall and injuries. It is also evident

that IAH has significantly affected the personal and social life of patients. These findings are in tune with another qualitative study among type 1 diabetic patients by Rankin et al, which reported that the patients were adopted marked life restrictions due to IAH (Rankin et al., 2014)

Though fatigue was a fairly universal problem highlighted, it is hard to delineate the fatigue associated with recurrent severe IAH from the general fatigue syndrome commonly seen in the dialysis population (Bossola et al., 2023). However, these physiological effects have a substantial burden on these patients' lives. Financial hardships in ESKD and dialysis was much studied (Ng et al., 2021) It could be inferred that the unpredicted nature of IAH predispose this already fragile patient population to more troubles in terms of frequent hospitalization, injury, financial burden and much more.

The study has recruited patients irrespective of their diabetic status and IAH is prevalent in non-diabetic dialysis patients also. Being on dialysis is not an individual matter alone rather, it encompasses all dynamics and complexities of a frazzled family. It is well known from prior studies that the role of family is vital in the management of chronic diseases like CKD (Gahatraj et al., 2023). Our interview findings also underlined this fact. Family support and planned proactive measures could benefit patients from the unforeseen events associated with an IAH spell. On the other extreme, the distress and burnout of the family were also evident in the interview. Many studies in the literature have discussed the family experiences with hypoglycemia, but that is beyond the scope of this study (Rankin et al., 2014). Another time tested strategy - patient education also get highlighted in this study. Both patient and family agreed on this in the qualitative segment but the study could not estimate this in numerical terms. However, collective efforts by patients and their families will definitely facilitate precise tracking and management of blood sugar values and bringing about considerable relief in patient experience.

The present study findings direct to the importance of an individually tailored patient management as the attribute of IAH is highly varies between individuals. Ongoing support and proactive life style modifications may reduce the risk of complications associated with IAH and may enhance patients' quality of life. Though the comprehensive approach in hypoglycemia is well explored, the IAH as a clinical entity has not studied generally so far. The study by Catriona et al. and Timón et. al. have emphasized on the importance of a holistic structured strategy ranging from identifying the at risk individuals, designing educational and technological interventions and effective involvement of family in the reduction of complications of IAH (Farrell & McCrimmon, 2021).

Conclusion

The aim of the study was to assess the prevalence of impaired awareness of hypoglycemia and to explore the patient and other significant stakeholder's perspectives on this. It is found that impaired awareness of hypoglycemia is significantly high among these patients and many factors such as age, being diabetic and the number of hypoglycemia associated hospitalizations have a predictive potential. This mixed method study on impaired awareness of hypoglycemia has brought about an insight to the hitherto less recognized issue among dialysis patients. A comprehensive approach by involving all the patient stakeholders may open up ways to address this issue among patients on hemodialysis.

Strengths and Limitations

Our study has tried to study the construct of IAH comprehensively through a mixed method approach. Within our knowledge not much studies have done to assess the prevalence of IAH among dialysis population in India that too through mixed method research.

Our study has many limitations. As it is a single center study, it lacks generalizability. Certain pertinent variables like years of insulin use and type, the role of previous exposure to diabetic education, dietary habits were not studied.

Conflict of interest statement

The authors declare that they have no known competing interests with regard to the work.

Ethics

The study was approved by the institutional research committee and institutional ethics review board. A detailed explanation regarding the study was given to all the participants. Separate written informed consent for both phases was obtained from every participant prior to enrolment. Ensured the confidentiality of collected data and voluntariness of participation. The study followed all prevailing ethical guidelines. No physical, psychological or financial burden was enforced on the participants.

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