

AN OBSERVATIONAL STUDY TO ADDRESS THE CHALLENGES IN INSULIN STORAGE AMONG PHYSICIANS

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Received : 24/12/2023
Received in revised form : 18/02/2024
Accepted : 02/03/2024

Keywords:

Diabetes, insulin, insulin storage, indigenous methods, physicians.

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DOI: 10.47009/jamp.2024.6.2.93

Source of Support: Nil,

Conflict of Interest: None declared

Int J Acad Med Pharm
2024; 6 (2); 430-434



Abstract

Background: Insulin is prescribed for both type-1 and resistant type 2 diabetic patients to attain optimum glycaemic levels. Insulin is a temperature sensitive protein; hence inappropriate storage affects its potency. Insulin which is not in use, should be stored in refrigerator where as in-use insulin can be stored up to four weeks at room temperature. Few of the remote areas of India are still facing appropriate electricity issues. Hence, the present study aimed to explore the physician's perception on various insulin storage methods at different situations.

Materials and Methods: A questionnaire-based study was conducted among physicians across the India during a specified time frame. The study focused physician's awareness on various insulin storage methods and practices, via a multiple-choice questionnaire. **Result:** A total of 150 physicians has completed the study. A total of 101 physicians (67.3%) prescribed refrigerator as insulin storage at home. If electricity and refrigerator are not available, most of them are following mixed methods of storage (n=28, 18.7%) followed by ice bag (n=8, 5.3%) and clay pot (n=6, 4.1%) respectively. Ice packing (n=53, 35.3%) and thermos flask (n=33, 22.0%) are the most commonly recommended methods of storage while travelling. More than half (n=78, 52.0%) of the physicians were not aware regarding literature available on validation of insulin storage. **Conclusion:** One of the best ideal methods of insulin storage is refrigerator. Although they are practising indigenous methods, nearly 80% of physicians lacking confidence due to lack of supporting studies on validation of those methods. Physicians are in ethical dilemma while prescribing various indigenous methods at home and while travelling.

INTRODUCTION

People from both developed and developing countries with their higher or lower socioeconomic strata are equally affected by diabetes mellitus (DM).^[1] In type-1 DM, insulin is the main treatment option. In addition, insulin also prescribed to the type-2 DM patients who are not controlled by oral hypoglycaemic drugs.^[2] Insulin, which is using daily for subcutaneous, can be kept at room temperature, however, which is not in use, should be placed at specific storage conditions to get desirable therapeutic effect.^[3,4] There are several issues and hindrances for proper storage of insulin which includes, lack of refrigerator at homes,^[5] interrupted power supply, non-availability of non-electric power supply and millions are facing other cooling access challenges. If above mentioned facilities are available at their homes, due to lack of patient counselling and health education, people with DM (PwD) are not following the practices of proper insulin storage.^[6,7]

Educating the diabetic patients regarding appropriate storage of insulin is the most important aspect before prescribing the drug for adequate control of blood sugar levels. Therefore, both prescribers, persons with diabetes should aware of insulin storage methods particularly who lives in resource-challenged, underserved areas.^[8-10] Hence, the present study was aimed to assess the physician's awareness on various insulin storage methods and also to evaluate their perceptions on various indigenous storage methods and their advice to PwD.

MATERIALS AND METHODS

Study Design, Period and Setting: A questionnaire-based study was conducted among physicians across the India between June 2023 and September 2023. Trained Indian physicians who were treating diabetes patients were included. Self-willing consent was obtained from physicians who were participated in the study. The study focused on assessing the details of the physicians who were

participating as well as their awareness of insulin storage methods and practices, via a multiple-choice questionnaire. [Table 1]

Data Collection: Detailed information related to physicians such as: (i) their highest qualification, (ii) whether they were treating people with type 2 diabetes, (iii) whether they were treating people with type 1 diabetes and (iv) whether they had prescribed insulin to such PwD. In addition to the physician details, the questionnaire also included details on the advice which was given by the physicians to the PwD who took insulin, about the storage of insulin at home and the transport of insulin during travel. The questions in the study were : (i) the prescribed insulin storage method (ii) the storage method used while travelling, (iii) regarding awareness of the articles written about the validation of clay-pot storage method, and (iv) whether study plans of validating clay pots and other indigenous methods of insulin storage might be crucial in helping its safe storage.

Statistical Analysis: Descriptive analysis was the method of choice for this questionnaire-based study in calculating the percentages of study participants under different categories of response.

RESULTS

Study Participants: Proportion of study participants treating diabetes and prescribing insulin was showed in Table 2. A total of 150 physicians has completed the questionnaire which was shared to them. Physicians who were treating diabetes were included in the present study. Out of 150 study participants, n=132 (88.0%) were prescribing insulin for their patients. Even though few physicians were not prescribing insulin (n=18), but they responded to the questions in the questionnaire regarding how they prefer in the future if situation arises.

Prescribed methods of insulin storage at home: Physician prescribed methods of insulin storage at home for people with diabetes was showed in Figure 1. A total of 101 physicians (67.3%) prescribed refrigerator as insulin storage at home. If electricity and refrigerator are not available, most of them are following mixed methods of storage (n=28, 18.7%) followed by ice bag (n=8, 5.3%) and clay pot (n=6, 4.1%) respectively. A quite low percentage of physicians (n=5, 3.3%) has not responded to the question as well.

Prescribed methods of insulin storage while travelling: Physician recommended methods of insulin storage while travelling was showed in Figure

2. Ice packing (n=53, 35.3%) and thermos flask (n=33, 22.0%) are the most commonly recommended methods of storage while travelling which contributes nearly 50.0% of total available methods. Clay pot (n=28, 18.7%) and ice bag (n=12, 8.0%) are recommending few physicians based on their previous experience. No clear preference was given by few physicians (n=16, 10.7%) where they are in ethical dilemma to recommend any specific methods of insulin storage while travelling.

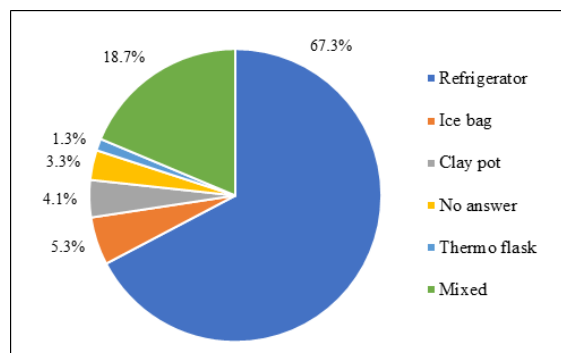


Figure 1: Physician prescribed methods of insulin storage at home

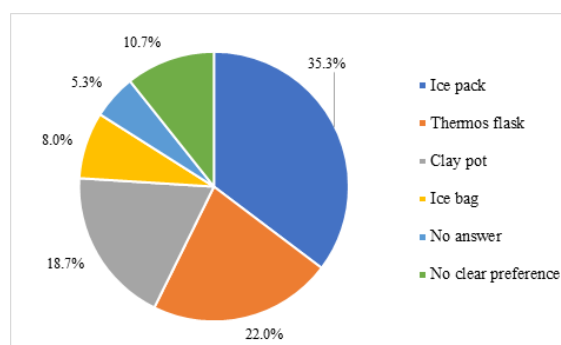


Figure 2: Physician recommended methods of insulin storage while travelling

Awareness and opinion regarding validation studies on various insulin storage methods: Awareness and opinion regarding insulin storage validation studies was showed in Table 3. More than half (n=78, 52.0%) of the physicians were not aware regarding literature available on validation of insulin storage. Views regarding the need of validation studies for indigenous storage methods, n=119 (79.3%) wanted further validation data to gain confidence for prescribing such methods, while 21 (14.0%) physicians were of the opinion that no such validation data was needed for them to prescribe.

Table 1: Questionnaire used in the present study

Question	Options
Your highest qualification	MBBS DM Others (please specify)
Do you treat patients with diabetes?	Yes No
If you treat patients with diabetes, do you prescribe insulin?	Yes No
Do you treat patients with type 1 diabetes?	Yes

	No
If you prescribe insulin, what method of storage do you prescribe?	Refrigerator Clay pot (matka) Ice bag Thermos flask
What method do you advise while travelling?	Ice pack Thermos flask Ice bag Cool pouch
Are you aware of the literature about the validation of clay pots?	Yes No
Do you think a study plan to see the validation of clay pots and other indigenous methods would help?	Yes No

MBBS=Bachelor of Medicine and Bachelor of Surgery; MD=Doctor of Medicine; DM=Doctorate of Medicine

Table 2: Proportion of study participants treating diabetes and prescribing insulin

Physicians	Number (%)
Total participants	150 (100)
Treating diabetes	150 (100)
Insulin prescribers	132 (88.0)
Insulin non-prescribers	18 (12.0)

Table 3: Awareness and opinion regarding insulin storage validation studies

Category	Number (%)
Awareness regarding literature on insulin storage validation	
Yes	65 (43.3)
No	78 (52.0)
No answer	7 (4.7)
Opinion on the need for validation studies in the future	
Yes	119 (79.3)
No	21 (14.0)
No answer	10 (6.7)

DISCUSSION

This study was done to assess the pattern of prescriptions and perceptions of 150 Indian physicians for insulin storage as there is a crucial role of appropriate storage methods for achieving the desired effects of insulin therapy and the physicians play a key role in this context of prescribing various insulin storage methods. Physicians who are treating diabetes was selected for this study, out of which 88.0% were prescribing insulin. Related to the prescription of storage methods for insulin, most of the physicians (67.3%) prescribed the use of a refrigerator at home while the use of ice packs (35.3%), thermos flask (22%) and Clay pot (18.7%) was most commonly prescribed while travelling.

However, the use of indigenous methods like clay pots is a good alternative for insulin storage since electricity is still a problematic feature in certain areas of the world.^[11,12] In place of refrigerators, it was advised that insulin should be kept in a dark place in absence of humidity as well as moisture, and minimum or no exposure to direct heat sources or sun rays.^[13–15] Several traditional and unconventional methods have been thus developed for the storage of insulin as a result of compromised resources and are being used in various countries, such as India, Tanzania, Sudan, Pakistan, Mali, Ethiopia, and Haiti.^[3]

Evaporative cooling-based clay pots filled with water to store insulin are the most commonly used technique by multitude of families in countries constrained by limited resources. Here, the variants

of unconventional methods of insulin storage are pot-in-pot refrigerators or the Zeer pot, mud pots, goat skin pots filled with water, vegetable gourds filled with water, and buckets filled with wet sand.^[3,16,17] An observation of these methods shows that the temperatures achieved by these devices are almost at or near room temperature, even in hot climates. But the principle of evaporative cooling cannot keep away humidity therefore these devices are more efficient at lower ranges of humidity. One-fourth of the physicians participating in this study, prescribed the use of clay pots for insulin storage when there is no electricity.

According to the United States Pharmacopeia (USP)/the United States Food and Drug Administration (FDA) criteria, at least 95% of intact insulin (equivalent to 95 U/mL) is required upon release. Therefore, the amount of intact insulin is measured quantitatively in various ways.^[18,19] Here, it is essential to know that most of the studies on insulin stability are conducted in western countries wherein room temperatures are usually below 25°C whereas in tropical countries, room temperatures are usually higher. In India, some areas, have temperatures well above 25°C throughout the year. Under these specific circumstances, the extraction of data from the studies of western countries when applied to the Indian scenario is a bit questionable.^[20] Owing to lesser opportunities, very few studies have estimated the effects of higher room temperatures on the quality of insulin. The cut-off value for the insulin potency, as recommended by the Indian Pharmacopoeia, is at least a decrease of 10%.

However, a study by Vimalavathini et al. showed that at higher temperatures (32°C and 37°C), the potency of both regular and biphasic insulin from different brands reduced by 14%–18% after three weeks.^[21]

It also presented the following outcome that in the absence of a refrigerator, in a country like India, insulin can be stored at room temperature for up to two weeks. Individuals hailing from rural areas in India, not having refrigerator facilities, are advised by health professionals to store insulin in mud pots. The internal temperature of mud pots is usually a few degrees lower than the normal room temperature. However, during summers, when there is an increase in room temperature, the internal temperature of mud pots can rise even beyond 35°C. In this condition, insulin stored in a mud pot is prone to denaturation.^[22,23] Therefore, it is of great importance to develop more such indigenous methods for proper insulin storage suitable for the diverse climatic conditions across a country like India.

In addition to that, validation of indigenous methods using different ways like bioassay on type-1 diabetic cell lines and mouse models should also be emphasised, to promote the implication of indigenous methods in our country.^[24,25] Almost 80% of the physicians in our study needed validation studies for the knowledge of understanding insulin stability during the usage of indigenous methods of storage like clay pots. This particular data signifies the utter need for validation of indigenous methods for insulin storage, in order to promote their prescription by physicians amongst individuals taking insulin therapy at home and while travelling.^[26] The important summary points and recommendations developed from the study have been presented in [Table 4]. Main highlight in this study is this aforementioned ethical dilemma, seen in nearly 80% of physicians advising non-refrigerator methods for insulin storage where there is a lack of electricity supply or availability of a refrigerator.

Table 4: Summary of key points and recommendations suggested from the present study

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| <ol style="list-style-type: none">1. One of the very few studies available on the perception of insulin storage among physicians2. Ice bag and clay pots were the commonest methods prescribed by physicians where electricity and refrigerators are not available3. Nearly 50% of physicians were preferred ice pack and thermos flask to store insulin while travelling4. More than three-fourths of the physicians wanted validation studies on various indigenous methods for better understanding of insulin stability |
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Strengths and limitations of the study: According to our knowledge, only couple of studies are available on the perception of insulin storage methods amongst physicians, which is the main strength of the present study. Additionally, a majority of insulin-prescribing physicians registered for the study exclusively from India, which is a developing country, crediting more novelty to the study. In developing countries, the availability of electricity and the inability of

purchasing refrigerators are major constraining factors for the storage of insulin, our study is valuable for the emphasis on the evaluation of indigenous storage methods prescribed by the physicians.

However, this study suffers from a few limitations. There might be a bias, since a few physicians might have answered casually in this study being questionnaire-based. In order to overcome this limitation, the number of physicians included in the study was more in number, including those physicians who did not treat diabetes or who were non-insulin prescribers also, to make it all inclusive. These physicians took part and completed the study based off on their knowledge and perceptions, as opposed to their actual clinical practice. In this study, the demographic data of the physicians were not included in the study, such as years of clinical experience, age, and gender. Therefore, the impact of these factors along with their highest qualification on insulin storage prescribing practises, and awareness of indigenous storage methods and validation studies could not be established properly.

CONCLUSION

One of the best ideal methods of insulin storage is refrigerator. Developing countries like India, an alternative, cost effective, near to ideal methods are required due to lack of complete electricity sources. Although various indigenous storage methods are followed among physicians in the present study, awareness of insulin validation is low. Though they are practising indigenous methods, nearly 80% of physicians lacking confidence due to lack of supporting studies on validation on those methods. If available, those studies were conducted in western countries, such date cannot be extrapolated to Indian scenario.

Results from this study clearly states that physicians are in ethical dilemma while prescribing indigenous methods. This study will motivate the researchers to initiate the validation studies on various indigenous methods on insulin storage which is highly warranted. There are very few studies emphasised on these issues, until further research studies conducted on this field, every physician who is prescribing insulin should aware of such studies. Physician has to advocate the other indigenous insulin storage methods with more conviction if refrigerator is not an option. Regardless of people with diabetes they live, insulin prescribers need to have a better awareness and should have trust if they are recommending various insulin storage methods.

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