

The insulin sharps disposal study: Evaluation of a structured patient education initiative in an urban community health centre in India

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ABSTRACT

Context: India has witnessed an increase in people suffering from diabetes mellitus and also those on insulin. The issue of handling used sharps in the community is an area of concern. **Aims:** Our study aimed to assess the change in knowledge and practise concerning the disposal of used insulin sharps in patients with diabetes, pre- and post-evaluation, a structured, health provider-initiated, patient-centred insulin-use health education (PIHE) **Settings and Design:** A pre- and post-evaluation study of PIHE set in an urban health centre in south India **Methods and Materials:** A pre-evaluation study was done on a cross-sectional sample of type II diabetes patients, who visited the urban health centre and were on insulin for at least 1 year. A semi-structured pilot-tested questionnaire was used for the study. For 18 months, PIHE was provided to all insulin users at outpatient contact, after which a post-evaluation study among another cross-sectional sample of patients in the same centre, was done to assess change in knowledge and practise. **Statistical Analysis Used:** Univariate analysis followed by logistic regression. **Results:** The participants in the pre- and post-evaluation studies had a mean (SD) age of 54.9 (11.33) years and 57.2 (11.01) years, respectively. The baseline characteristics of gender, socioeconomic status and diabetes duration were similar. There was a statistically significant ($P < 0.001$) difference in knowledge (19 [19%] to 81 [81%]) and practise (7 [7%] to 73 [73%]) of participants regarding the correct disposal method of used insulin syringes and sharps before and after PIHE. **Conclusions:** PIHE over an 18-month period for diabetic patients on insulin significantly improved knowledge and practises relating to insulin use and correct disposal of syringes and sharps.

Keywords: Community healthcare, health education, insulin sharp disposal

Introduction

The Food and Drug Administration, U.S.A has defined sharps as ‘medical term for devices with sharp points or edges that can puncture or cut skin’. These could be used in different settings like home, work, hospital and in transit to manage an array of medical conditions.^[1] The World Health Organization (WHO)

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estimates that about 16 billion injections are administered every year, but not all sharps wastes are disposed of safely.^[2] While sharp disposal is strictly regulated in most hospital settings, this is not the case in the community. Across the world, studies show that a majority of patients with diabetes dispose of used sharps inappropriately in household garbage.^[3,4]

In India, the Central Pollution Control Board has set criteria for the disposal and recycling of sharps in the hospital settings.^[5] However, apart from the National AIDS Control Organisation (NACO), guidelines on safe community disposal of used sharps in the context of intravenous drug users; there are no clear guidelines/systems in place for home/community disposal of used sharps.^[6] Without guidelines, systems for sharps waste disposal and lack of health provider advice on the issue may lead to blood-borne infections in waste collectors and scavengers.

In India, the subset of sharp users is significant; about 65 million Indians who have diabetes use 160 million syringes and about 50 million pen needles every year.^[7] The prevalence of diabetes in our country has increased over the past few decades from 2% in the 1970s^[8] to 8.9% in 2020.^[9] The results of the Indian Council of Medical Research-INDIAB study published in 2017 in *The Lancet*, reported a prevalence of 7.3% across 15 states in India.^[10] The INDIAB study also showed that among those who self-reported diabetes in India; around 10% were on insulin. Another disease-burden estimation study in India, published in 2018 showed that the number of people with diabetes increased from 26 million in 1990 to 65 million in 2016.^[11]

The Indian Injection Technique Study done in 2016, as a part of a large multicentre global study to assess the technique of insulin users shows that 60% of the used sharps in India are disposed of like general rubbish and the sharps are disposed of without the cap among 12%.^[12]

Literature shows that support provided by members of the healthcare team promotes adherence and glycaemic control among diabetics.^[13] There is evidence that patients are more likely to dispose of sharps appropriately if advised by healthcare providers.^[14] Patient behaviours, when influenced by regular diabetes education in self-care have shown to improve outcomes in patients. A one-time intervention is not enough and ongoing support is required from the healthcare team.^[15] Primary care physicians are the first point of care for patients with diabetes mellitus and are usually easily available to patients as compared to specialists.^[16] As the primary member of the healthcare team, primary care physicians are in charge of translating their knowledge and confidence to the patient.^[17] India's flagship programme: National programme for prevention and control of cancer, diabetes, cardiovascular diseases and stroke (NPCDCS) has operational guidelines for managing diabetes at a primary level.^[18] It is, hence, vital that every aspect of diabetes management including disposal of used insulin sharps is explicitly counselled to the patient by primary care physicians and the health-team.

Based on this literature; in our study, we looked at type II diabetes patients on insulin and how they disposed of their syringes and sharps before and after a structured health provider-initiated patient-centred insulin-use health education (PIHE).

Subjects and Methods

The study was a pre- and post-evaluation of PIHE, conducted in 2015 and 2017, respectively. Two cross-sectional samples of type II diabetes patients, who visited the urban community health centre in Tamil Nadu, India were administered piloted semi-structured questionnaires after informed consent. Patients were included if they were on insulin for at least 1 year. Approval from the ethics committees has been obtained. Letter of approval is dated 07-07-2015.

The operational definition of 'patient-centred insulin-use health education (PIHE)':

A PIHE was a structured set of information imparted by the health provider (doctor or nurse educator), in our setting. It was focused on understanding the patient's home environment and essentially included the following points

1. Preferable site for insulin injection is the abdomen
2. Insulin injections sites should be rotated
3. Insulin syringes are single-use
4. Insulin to be stored in a refrigerator (if not available, other locally relevant suggestions like the double-earthen pot method)
5. Used insulin syringes and needles should not be disposed of in the household waste
6. Used insulin syringes and needles should be returned in a puncture-proof container to the health facility (like a steel container with a tight lid; to be brought back during follow-up visits. Precautions to keep such containers out-of-reach of everyone at home were provided)

The study was conducted in an urban community health centre of a tertiary care hospital in Tamil Nadu, India. The centre caters to an urban population of 200,000 by providing outpatient, inpatient and emergency services. The centre has 46 inpatient beds; two beds in the delivery room, and a single bed operating room. The healthcare team includes family medicine and community medicine specialists, nurses, medical officers, postgraduate trainees and interns.^[19] On a regular day, the outpatient department (OPD) witnesses about 200 patient encounters. The commonest reason (18.25%) for encounter in the OPD at the centre is diabetes follow-up and the commonest diagnosis (31.2%) was type 2 diabetes.^[20]

Sample size

The study population included patients with diabetes mellitus who visited the OPD, who had been on insulin for at least 1 year. We used this clause to ensure that the patient had a minimum of three contacts with the health facility, enough opportunity to

be advised about insulin use, storage and adequate disposal of sharps. A sample size of 41 in each group (pre- and post-PIHE) was calculated using the following calculation. P_1 = proportion of the sample who disposed of syringes in general waste = 80%.^[21] We expected a reduction in this practise by 20%, hence P_2 = 60%. We set the power at 80% and a confidence level of 95%.

$$P' = (P_1 + P_2)/2 \text{ and } Q' = 100 - P'. \text{ N in each group} \\ = [P' \times Q' \times (Z_{\alpha/2} + Z_{\beta})^2] / (P_1 - P_2)^2$$

Study tool: The semi-structured pilot-tested questionnaire was administered to patients after obtaining informed consent. The questionnaire had a section on socio-demographic factors of the respondent, duration of diabetes and insulin use, six questions on knowledge and nine on practises of insulin use. The questionnaire was translated to the local Tamil language and back-translated to English for validation. It was reviewed by a team of experts on the Institutional Review Board (IRB). The questionnaire was pilot-tested on a small group of patients in the in-patient section of the urban community health centre. The questionnaire was administered by the investigators depending on their availability in outpatient care.

Sampling and data collection

All the charts of patients with diabetes were scanned daily during the data collection period of 1 month in 2015 and 2017, respectively. Those on insulin for at least 1 year were enrolled in the study. The patients were enrolled consecutively to reach the sample size of 100 in the pre- and post-evaluation studies. All the patients seen in the OPD are from a strictly defined geographic area and it was fair to assume that these patients were representative of the population served by the urban community health centre. Though the pre- and post-evaluation was done on a sample of 100 each; the patient-centred health education in the 18 months between the data collection was aimed to be offered at all patient encounters. In the pre-evaluation study (July-August 2015), after the study tool was administered, each participant was advised regarding setting-appropriate sharp disposal practise. The results of the pre-evaluation study were shared by one of the investigators through a formal session with the health personnel in the facility, who, in turn, reinforced PIHE. PIHE was followed for all patient encounters subsequently. The post-evaluation study (February-March 2017) was done 18 months later to see if there was a change in the knowledge and practise of the insulin users in the facility. Note that both the pre- and the post- studies recruited patients as per their visit to the OPD and that the same set of people was not followed up.

Statistical analysis

Data entry was done in epi-data software and data analysis was done using statistical package for the social sciences (SPSS) software version 16. All discrete variables were expressed as frequencies and percentages. The pre-evaluation and post-evaluation items were compared using Chi-square tests. The differences were reported as a percentage change.

The study was approved by the IRB of the tertiary care institute. The IRB Reference number was 9523, dated 07/07/2015.

Results

The participants in the pre- and post-evaluation studies had a median age of 55 years (interquartile range [IQR] 50–61) and 59 years (IQR 51–65), respectively. The baseline characteristics were similar across the two samples and there was no statistical difference between the two samples. The mean duration of type II diabetes mellitus among participants in both samples was 12.6 years (SD 7 years). The mean duration of insulin use was 2.7 years (SD 3.33) in the pre-evaluation group and 4.2 years (SD 4.36) in the post-evaluation group. But the difference was not statistically significant. The details of the same are depicted in Table 1.

The majority of our patients (98%) use insulin syringes to administer insulin. The knowledge and practises of participants in the two samples are shown in Table 2. There is a significant change in knowledge and practise of the site of insulin administration and disposal of used insulin syringes and sharps. However, there is an increase in the percentage of people who reuse their syringes. There was a significant increase in the practise of returning the used sharps in puncture-proof containers to the urban health centre; from 7% in the pre-evaluation study to 73% in the post-evaluation study.

A key change that the study aimed to bring about was to increase the awareness about PIHE among health personnel and patients. There is a significant difference in the proportion of the sample who received information from healthcare providers in the urban health centre as shown in Table 3, from 31% in the pre-evaluation to 86% in the post-evaluation study.

We conducted a logistic regression to determine the factors affecting the practise of correctly disposing of used insulin syringes. We used socioeconomic status, gender, education status and duration of insulin use as factors that may influence practise. The results of the logistic regression are presented in Table 4. In the pre-evaluation study, patients with higher socioeconomic status are more likely (adjusted odds ratio 14.16 [1.34, 14]) to dispose of used sharps appropriately, but after PIHE, in the post-evaluation study, the adjusted odds ratio reduces to 0.33 (0.09, 1.24).

Discussion

Our study shows that the mean age of patients in the pre- and post- evaluation study was 54.9 (11.33) and 57.2 (11.04), respectively. The majority (about 70%) were female and had type II diabetes mellitus for a mean (SD) of 12.6 (7.8) years. The mean duration of insulin initiation was 10.1 years (9.63) and 8.8 years (6.69) in the two groups. These are higher than a mean of 7 years, as reported by a multicentre study in India in 2012 (IMPACT study).^[22] An international study done in the

Table 1: Baseline characteristics in pre- and post-evaluation study

Baseline Characteristics	Pre-evaluation study* n=100	Post-evaluation study* n=100	P#
Age of participants in years	54.9 (11.33)	57.2 (11.04)	0.145
Gender			
Female	73 (73%)	70 (70%)	0.638
Male	27 (27%)	30 (30%)	
Socioeconomic class**			
Lower and upper lower class	95 (95%)	88 (88%)	0.076
Middle class and above	5 (5%)	12 (12%)	
Duration of Type II diabetes in years	12.6 (7.80)	12.6 (7.11)	0.980
Duration of Insulin use in years	2.7 (3.33)	4.2 (4.36)	0.09
Mean duration to insulin initiation in years	10.1 (9.63)	8.8 (6.69)	0.194

*Numbers presented as Mean (SD) or Frequency (Percentage %). #Using independent-samples t-test or Chi-square test where appropriate. ** Socioeconomic class was calculated based on the modified Kuppuswamy scale for 2017, as this was an urban population

Table 2: Knowledge and Practise regarding Site, Storage, Injection use and Disposal (Comparison between pre- and post-evaluation study)

Item of Knowledge/Practise	Pre-evaluation study n=100	Post-evaluation study n=100	P (Chi-squared test)
Preferable site to administer Insulin (abdomen)			
Knowledge	86 (86%)	98 (98%)	0.020
Practise	62 (62%)	94 (94%)	<0.0001
New syringe should be used once			
Knowledge	3 (3%)	1 (1%)	0.08
Practise single use	0 (0%)	0 (0%)	
Practise reuse more than thrice	77 (77%)	82 (82%)	0.001
Ideal storage of Insulin at home (Refrigerator)			
Knowledge	96 (96%)	100 (100%)	0.043
Practise	91 (91%)	95 (95%)	0.379
Ideal way to dispose used syringes (Return to health facility)			
Knowledge	19 (19%)	81 (81%)	<0.0001
Practise	7 (7%)	73 (73%)	<0.0001
Device used to administer insulin			
Syringes	98 (98%)	100 (100%)	0.364
Pen device	1 (1%)	0 (0%)	
Missing	1 (1%)	0 (0%)	

Table 3: Whether the insulin user received advice from health care professionals regarding insulin sharps disposal

	Pre-evaluation study (n=100)	Post-evaluation study (n=100)	P (Chi-Square test)
The participant received information on how to dispose used insulin sharps	31 (31%)	86 (86%)	<0.0001

Table 4: Factors that determine Insulin syringe disposal (Logistic regression)

	Pre-Evaluation study (Practise of correct disposal of used Insulin sharps)		Post-Evaluation Study (Practise of correct disposal of used Insulin sharps)	
	Unadjusted OR (95% CI)	Adjusted OR (95% CI)	Unadjusted OR (95% CI)	Adjusted OR (95% CI)
Socioeconomic status (≥Class III Modified Kuppuswamy Classification)	12.0 (1.62, 88.93) P=0.02	14.16 (1.34, 149) P=0.02*	0.46 (0.14,1.62) P=0.23	0.33 (0.09,1.24) P=0.10
Duration of Insulin use (≥ 2 years)	0.41 (0.08,2.21) P=0.30	0.329 (0.05, 2.16) P=0.25	0.66 (0.23,1.86) P=0.44	0.71 (0.24, 2.11) P=0.54
Education of patient (≥ 10 years)	3.09 (0.65,14.75) P=0.16	1.78 (0.32, 9.83) P=0.51	1.61 (0.49, 5.34) P=0.43	2.35 (0.65, 8.52) P=0.193
Gender (Female)	0.91 (0.17,5.05) P=0.92	0.69 (0.10, 4.56) P=0.69	2.44 (0.96, 6.17) P=0.06	3.07 (1.14, 8.25) P=0.03

*In the pre-evaluation study, the higher socioeconomic status of participants was significantly associated with correct disposal of used insulin sharps

Netherlands in 2016 showed that the mean insulin initiation time was 1.2 years in those with HbA1c levels consistently ≥7.0%

and was 5.4 years in those with varying HbA1c levels around 7.0%.^[23] The context plays a huge role in this aspect and various

patient and physician factors contribute to the mean duration from diagnoses of type II diabetes mellitus to insulin initiation.^[24] Most people in this study belonged to the lower or upper-lower socioeconomic class as per Kuppuswamy classification. The reason for this is that the urban centre in our study provides care specifically to the lower economic strata from a fixed geographical area.

The knowledge and practise of preferring the abdomen as a site of insulin administration have increased from the pre- to the post-evaluation study. This is as per the New Insulin Delivery Recommendations, 2016.^[25] This guideline also recommends single use of a new insulin syringe, but there are cost factors involved in not implementing this recommendation. A systematic review done in 2016 concludes that there is no clear evidence that goes for or against the reuse of needles for insulin administration.^[26] A known adverse effect of reuse is lipodystrophy, and a study done in Brazil in 2015 reported that the estimated economic impact of reusing syringes is much higher due to increased complications and insulin-use than if syringes were not reused.^[27] Our study showed that 77% ($n = 77$) in the pre-evaluation group and 82% ($n = 82$) in the post-evaluation group reused syringes for more than three times. This is probably because of the high cost-burden on individuals due to their condition. A study published in 2020 shows that individuals spend between INR 8000 to INR 45000 per year in India depending on which zone they live in.^[28]

A study done in a large Indian cohort in 2017 showed that 66% used pen devices and 32% used insulin syringes. In this study, most people were from middle-high income households.^[29] A study published in 2020 in Bangladesh showed that 68% of patients used pen devices and 32% of patients used syringes.^[30] This is different from what we find in our study, where almost 100% of users use syringes and most patients belonged to low- and middle-income families.

The study published in 2020 from Bangladesh showed that 69.3% disposed sharps into rubbish after recapping and 12.4% disposed of sharps without recapping into the rubbish.^[30] Our pre-evaluation study showed that 67% disposed it in garbage bins and 7% returned used syringes to a health facility. The post-evaluation showed statistically significant improvement to 25% and 73%, respectively. Our study also shows that the participant reporting of having received information on the correct disposal of used syringes increased from 31% to 86%.

A study done by Cunha *et al.* in 2016 in Brazil, among primary care patients, showed that age, gender, education and occupation status were not associated with correct disposal.^[31] In our pre-evaluation study, the higher socioeconomic status of participants was significantly associated with the correct disposal of used insulin sharps. The post-evaluation regression analysis showed no significant association between gender, education, socioeconomic class and duration of insulin use with correct disposal.

The injection study from Bangladesh shows that though 92% of the insulin users received initial counselling about insulin use and disposal; only 32% had a repeat counselling in the last 6 months since the survey.^[30] The poor practises in this study strengthen the evidence from our study that repeated revisiting of counselling by health team members is required for patients with diabetes.

Primary care physicians need to keep these findings in mind and review key insulin use and disposal practises at every visit with patients to improve good practises among patients.

Most studies in literature in the area of insulin knowledge and practise among patients are cross-sectional studies. Our study is unique in a way that there are two parallel cross-sectional studies separated by a time-interval where PIHE was given to patients with diabetes. Our study shows that reinforcing the key principles of insulin-use and disposal over 18-months improves knowledge and practises among patients, except the number of reuses of syringes (probably related to the affordability of the participants in our study).

Our study showed that there was an increase in the number of patients who had been advised regarding insulin use by a healthcare professional; there was an increase in patients who injected insulin into the correct site, who stored insulin in the refrigerator and who disposed of used insulin sharps correctly (in our case, return to the facility in a puncture-proof container).

Limitations

The study assessed practises by a questionnaire and not by direct observation. Further, the questionnaire was administered by investigators who were the treating physicians of the participants and who also provided health education to some of the participants during earlier visits. Hence, there is a possibility of over-reporting of desirable sharp and syringe disposal practises.

The study was conducted in an urban community health centre that caters primarily to the lower socioeconomic strata of the area. Hence, the study results may not be generalizable to the general population.

Conclusion

PIHE over 18 months in diabetic patients on insulin significantly improved knowledge and practises relating to insulin use and correct disposal of syringes and sharps. The increasing number of type II diabetes patients on insulin necessitates PIHE throughout patient care.

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Conflicts of interest

There are no conflicts of interest.

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