

Review Article

Forum for Injection Technique (FIT), India: The Indian recommendations 2.0, for best practice in Insulin Injection Technique, 2015

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ABSTRACT

As injectable therapies such as human insulin, insulin analogs, and glucagon-like peptide-1 receptor agonists are used to manage diabetes, correct injection technique is vital for the achievement of glycemic control. The forum for injection technique India acknowledged this need for the first time in India and worked to develop evidence-based recommendations on insulin injection technique, to assist healthcare practitioners in their clinical practice.

Key words: Adherence, aspart, degludec, detemir, diabetes, education, glargine, glucagon-like peptide 1 receptor agonists, glulisine, injections, injection sites, injection technique, insulin, insulin analogs, lipohypertrophy, lispro, needle length, skin-fold, storage

INTRODUCTION

An alarmingly rising prevalence of diabetes has been reported in recent years.^[1] According to current studies, 67 million

Indians are affected with diabetes.^[2] By 2030, the prevalence of diabetes among Indians is projected to reach 87 million.^[3] Insulin remains the mainstay of treatment in diabetes^[4] and about 3.2 million Indians depend on insulin injections for the management of diabetes.^[5] Many people with type 2 diabetes and all with type 1 diabetes need insulin for survival, and intensive insulin therapy is recommended in them.^[6] However, incorrect technique of injecting insulin may increase the risk of poor glycemic control, due to mismatch of peak insulin effect and maximal glucose load.^[7,8] Shorter needles are beneficial over longer ones as they avoid the risk of intramuscular administration even if injected at 90° angle

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to the skin surface.^[9] It has been demonstrated that the use of shorter needles provides equivalent glycemic control compared to longer needles, without increasing the incidence of leakage events. Shorter needles also help in combating the psychological fear of needles in patients and hence improve their acceptance of insulin injection therapy.^[10]

Improper use or reuse of injection devices, like needles, may lead to undesirable consequences including pain with bleeding and bruising, breaking off and lodging under the skin, contamination, dosage inaccuracy, and lipohypertrophy.^[11] According to a study, correct injection technique and use of shorter needles (4 mm) are associated with improved glucose control, greater satisfaction with therapy and lower consumption of insulin after only a 3-month period.^[12] Appropriate injection technique, thus, is an indispensable part of diabetes management.

NEED FOR INDIAN RECOMMENDATIONS

Appropriate injection technique is crucial for the success of insulin therapy. Several issues such as lack of knowledge, time constraints of healthcare providers (HCPs), and scarcity of local recommendations may contribute to the lack of appropriate injection technique.^[13] Physicians' awareness and willingness to convey basic information such as the dosage, injection site selection, depth of injection, and the correct method of injection go a long way in preventing faulty injection technique.

However, there are some factors such as dexterity, visual and hearing impairment, and learning skills which at times cannot be modified. These factors can be addressed by choosing appropriate insulin devices, suited to the individual.

Recommendations or consensus statements on an insulin technique that suit the local needs of developed countries are available. Such documents have not addressed certain issues relevant to developing countries such as India. Hence, a need for Indian recommendations for best practice in insulin injection technique was felt.

MATERIALS AND METHODS

The first draft of the forum for injection technique (FIT) India recommendations, 2012, was prepared by a core writing group of three endocrinologists. A psychiatrist was co-opted into the core writing group to provide expert opinion on the psychological aspects of injectable therapy.

The methodology of literature search, medical writing strategy, and evidence grading was finalized after consensus approval and validation by a board of 13 HCPs from various medical

disciplines, including endocrinologists, diabetologists, diabetes educators, psychiatrists, and psychologists. Simultaneously, the draft was also reviewed by 76 clinicians from India and six experts from South Asia (South Asian referral group). Another five eminent members were added to the FIT India advisory board in November, 2014.

These recommendations are based on the evidence collated from published literature, specific to the subject of injection technique. The grading method followed by Frid *et al.* (2010), which includes an activities-specific balance confidence scale for the strength of recommendation and 123 scale for scientific support, has been used to grade the evidence [Figure 1].^[14] Certain recommendations, which are supported by manufacturer advice or drug authority guidance, have been ranked 1 in scientific support.

An abridged version of the recommendations was published in Indian Journal of Endocrinology and Metabolism. An addendum was published in 2013 to cover certain issues which had not been included in the original FIT India document. An expert on insulin pump therapy was co-opted while writing the addendum.

Another addendum has been published in 2014, with the aim of making FIT India more comprehensive.

The revised FIT India recommendations, 2015, have been prepared carefully to ensure that no relevant information is omitted, and no superfluous information added.

INJECTION TECHNIQUE RECOMMENDATIONS

Preinjection assessment

Clinical assessment

A thorough patient assessment should precede therapy initiation (B3). Optimization of injection technique with respect to the individual patient needs is critical for the success of injectable therapy.^[11]

ABC Scale:	123 Scale:
Strength of recommendation	Scientific support
A: Strongly recommended	1: At least one randomised controlled study
B: Recommended	2: At least one non-randomised (or non-controlled, or epidemiologic) study
C: Unresolved issue	3: Consensus expert opinion based on extensive patient experience

Figure 1: Grading criteria (Frid *et al.*, 2010)

Environmental assessment

The use of correct type and device of insulin should be ensured. As the insulin is sensitive to extreme temperatures, it is essential to inquire about storage conditions of injection supplies (B2). Availability of stock for at least 1–3 months should be ensured so that no dose is missed. If injection cold storage facilities are not readily available, insulin pens can be used instead of vials (C1).

Sociocultural sensibilities

Sociocultural sensibilities of the community should be respected. It is advised to discuss the site of injection beforehand in Indian women so that their sensibilities are not offended.

Preinjection counselling

More than ¼ of patients may refuse insulin therapy after prescription.^[15] This phenomenon is often termed as psychological insulin resistance (PIR). The most pronounced reasons associated with PIR are personal failure, anticipated pain, low self-efficacy, and lack of awareness about the benefits of insulin.

It is thus essential to encourage shared decision-making with active participation of the patient. Specification of pain-minimizing devices, like pens requiring low pressure for injection, in the doctor's prescription, could help in insulin therapy initiation.^[14]

Children

In the early stages of diabetes, especially in childhood, the diagnosis of diabetes creates a sense of distress and anxiety in both parents and children. This hinders parents' ability to administer insulin or encourage children to self-administer insulin (A1). Helping children to overcome their fear of needles is mandatory.

Initially, to overcome anxiety, it may help to allow parents and children to administer saline, insulin diluent or one unit of insulin themselves. Explanation of the role of insulin in diabetes management and the need for regular injections allays misconceptions and concerns. One may demonstrate injection technique on oneself, or on a toy doll. Play therapy is a useful method of explaining injection technique.

Adolescents

Adolescents may exhibit the sub-optimal compliance to insulin injection schedule due to several factors such as peer pressure, lack of seriousness, pain, and frustration (A2). Adolescents, especially girls, may skip insulin injections because of the fear of weight gain. It is important to help them overcome any possible misconceptions related to insulin by sharing information with them (B2). Re-emphasizing the

benefits of insulin administration helps increase acceptance of insulin injection among adolescents (B1).

Adults

All newly diagnosed persons with diabetes should be educated about the course of diabetes and the need to start insulin therapy at some time in the future^[14] (A3). It is important to explore and acknowledge concerns of the patients.

Elderly

Counseling geriatric patients for self-injection can be a challenging task. Limited dexterity, visual impairment, and hearing impairment are of utmost importance in this vulnerable group of patients.^[16]

The importance of modern pen devices is reflected best in the field of geriatrics. Their discreetness, simplicity, and convenience of use, dosage accuracy, and being less painful to inject allows for widespread acceptability amongst the elderly.^[17-19] Easy preselection of the prescribed insulin dose has also been well-documented.^[20] Various recommendations for diabetes management in the elderly have discussed these points and suggested some practical remedial steps.^[21]

Technical superiority of a product (analog vs. conventional) or an injection device (pen vs. syringes), should be given due consideration.

Injection storage

It is recommended that specific storage recommendations provided by the manufacturer be followed. Insulin should be stored in a cool and dark place. Insulin pens and vials, which are not being used, should be refrigerated, but not frozen (A1). If frozen, insulin should be discarded. Insulin being used can be kept at room temperature to limit local irritation at the injection site, which may occur when cold insulin is used. The insulin vial should be taken out and kept at room temperature for at least 30 min before use.^[22] Pens should never be stored with needles on, because the higher risk of the air entering through the needles may clog them and hence affect dosage delivery.^[11] In rural areas or in places where a refrigerator is not available, it is advisable to put the vial in a plastic bag, tie a rubber band, and keep it in a wide-mouthed bottle or earthen pitcher filled with water. Insulin should be kept out of reach of children.

Travel: Surface

While travelling, insulin should be stored in a flask with ice, or in a handbag, or in a proper container if the outside temperature is >30°C. Insulin should never be kept in the glove compartment of a car or left in a locked car with closed windows.

Travel: Air

While travelling by air, one should ensure that:

- Physician should be consulted if travelling to a place with a time-zone difference of 2 or more h because it may require a change in insulin injection schedule^[23]
- Insulin should not be placed in the baggage hold of the plane due to the risk of exposure to extreme temperatures^[23]
- Extra insulin pen or vial should be carried so that insulin therapy is not interrupted in the event of device breakdown/malfunction
- The shelf life of insulin should be adequate for the duration of the trip.

Device selection and use

Prior to injection, the patient must verify the expiry date and the dose, and whether injection with the correct type of insulin is being prepared. Depending on the type of insulin, significant variations in the expiry dates of insulin vials or pens after opening may be reported (A1). Resuspension of cloudy insulin is important to ensure proper absorption of injected insulin and to maintain appropriate concentrations of the remaining insulin in the vial or pen^[18] (A2).

Syringe and vial compatibility

Dose

Both U-40 and U-100 insulin concentrations are available in India. While initiating insulin therapy, the patient should be informed that U-100 vials should be used with U-100 insulin syringes and U-40 vials with U-40 insulin syringes only. Insulin syringes of U-100 have an orange cover and black scale markings denoting two units each while U-40 syringes have a red cover and red scale marking denoting one unit each.^[24,25]

Needle size

Insulin syringes with three different needle lengths 6, 8, and 12.7 mm are available. Furthermore, three gauge sizes, 31, 30, and 29, are available in insulin syringes. The higher the needle gauge, the thinner the needle. A 31-gauge syringe is available in both 6- and 8-mm needle lengths.

Pens and pen needles

Insulin pens carry insulin in a self-contained cartridge.^[26] Different brands and models of insulin pens are available.^[27] Insulin pens are of two types: Reusable insulin pens, where cartridge can be reloaded; and disposable insulin pens, which are disposed once emptied.

Different types and brands of insulin are available for the pen. One should consider the number of insulin units the pen can hold when full and the largest dose that can be injected with it. Certain features of the insulin

pen such as adjustments of the dose by the pen based on the markings (two-, one- or half-unit increments) and indications on the pen to make sure whether or not there is enough insulin left in it for the entire dose, have additional benefits to the patient. The design and material of the pen, numbering on the pen dose dial and its magnification and the amount of strength and dexterity needed to operate the pen should be checked. Furthermore, one should check whether corrective measures are available if a wrong dose is inadvertently dialed into the pen.^[27]

Pen needles

Pen needles are available in 4, 5, 6, and 8 mm sizes and are of 32, 31, and 30 gauge.^[28] The shorter needles alleviate the risk of intramuscular injections while avoiding intradermal delivery as well. They are long enough to pass through the skin into the fat layer but are short enough not to reach the muscle tissue.^[29]

Needle length

A subcutaneous injection aims to deliver medication directly into the subcutaneous tissue without any discomfort or leakage. Ultrasound measurements reveal a mean skin thickness of about 2.2 mm. Multivariate analyses (of age, body mass index, ethnicity and gender in adults with diabetes) demonstrate that variation in skin thickness is not clinically significant.^[7] Hence, there is no medical reason to recommend needles longer than 4–6 mm to either children or adults. Extremely lean patients should be using a skin fold to inject even with a 4 mm and 5 mm needle.

Clinical studies have also reported equal efficacy and safety/tolerability of shorter needles (4 mm) in comparison to longer ones. A randomized trial compared the efficacy and tolerability of 4 mm and longer needles (5 mm and 8 mm) in adult diabetes patients. In addition to providing equivalent glycemic control and alleviating the risk of intramuscular injections, a 4-mm needle resulted in less painful injections and did not increase leakage events compared to longer needles. This study also reported that shorter needles were preferred by patients. Thus, shorter needles may obviate PIR and thereby help improve patient adherence to insulin injection therapy [Tables 1 and 2].^[10]

Needle length in children

Shorter needle length (4-mm) is considered safe and efficacious in children. Currently, a 4 mm pen needle is considered safest for all the children. However, when used in children aged 2–6 years, it should be used with a pinched skin-fold.^[30]

Table 1: Needle length: Recommendations

Children and adolescents
Children and adolescents should use a 4-mm needle with pens and the shortest needles available (currently 6-mm) with syringes (A2)
No clinical reason exists to recommend needles longer than 6 mm in children and adolescents (A2)
In children who are slim, when injecting into the limbs, a skin-fold is required: Especially when using a 5- or 6-mm needle (A1)
An injection angled at 45° with a 6-mm needle can be used instead of a skin-fold (A1)
If only an 8-mm needle is available, then they should lift a skin-fold and/or inject at 45° (A1)
Injection into the arms needs third-party assistance and a lifted skin-fold, for needle length more than 5 mm (A3)
Adults
Adults including obese patients can use 4-mm needle with pens and 6-mm long needles with syringes (A2)
Adults do not require the lifting of a skin-fold*, particularly for 4-mm and 5-mm needles (A1)
Shorter needles should be given in adults at a 90° angle to the skin surface (A1)
An injection into the limbs or a slim abdomen warrants the need for a skin-fold with needles longer than 5-mm (A2)
No clinical reason is available for recommending needles of length more than 6 mm in adults (A2)
Patients already using needles ≥8 mm should move to a shorter needle or lift a skin-fold and/or inject at 45° in order to avoid injecting into muscle (A2)

Table 2: Estimated intramuscular injection risk by body site

Needle length (mm)	Thigh (%)	Abdomen (%)
4	1.6	0.3
5	4.7	1.1
6	10.0	2.8
8	25.0	9.7
12.7	63.0	38.0

Injection site

A subcutaneous injection is the most commonly employed route for insulin administration in ambulatory patients. Other routes such as intravenous (I.V.), infusion, or intramuscular routes are employed only during ketoacidosis or stressful conditions.^[31]

Anterior abdomen

Abdomen is the most common site for insulin injections.^[14] The space around a horizontal line drawn 2.5 cm above and below the umbilicus and lateral to vertical lines drawn 5 cm away from the umbilicus may be utilized for subcutaneous insulin injections.

Upper arm

Over the arm, the injection site includes the upper lateral mid-third of the arm between the shoulder and elbow joint.

Anterior thigh

Over the thigh, the preferred site is in the anterior and outer aspect of the mid-third of the thigh, between the anterior superior iliac spine and knee joint.

Buttock

The upper outer quadrant of the buttock should be used. The upper outer quadrant may be located by placing index finger on the iliac crest and making a right angle between the index finger and the thumb. This site is not used routinely in adults. It can be used in infants and toddlers.

The order of the rates of absorption at these sites is abdomen > arm > thigh > buttock.^[32] The presence of a fat layer and only a few nerves in these regions makes injections convenient. Proper care of the injection site should be taken, as poor hygiene can lead to local infections.^[32]

Seven-step injection site care process

- Prior to injection, the site has to be inspected and palpated for lipohypertrophy and inspected for wounds, bruises or blisters (A3)
- If the injection site shows any signs of lipohypertrophy, inflammation, edema or infection, a different site should be selected (A2)
- Injection should be given at a clean site with clean hands (A2)
- If the injection site is found unclean, it should be cleansed prior to injection (A3)
- The injection site has to be inspected at every visit or at least every 6 months, or as part of the investigation into sub-optimal or erratic blood glucose control (A2)
- Rotate injection sites systematically (A2)
- Ideally do not reuse needles (A2)

Cleansing

Cleanliness of the injection site should be ensured before giving the injections. Cleansing is the single most important procedure for preventing healthcare-associated infections. The injection site may be thoroughly cleansed either with cotton balls dipped in water or with alcohol swabs (A2). Cleansing should be started in the middle and moving outwards in a circular motion, the whole area of the injection site should be properly cleansed. Alcohol on the skin should be completely dry before injection.^[14]

Skin-folds

Injections into skin-folds are considered when the presumptive distance from the skin surface to muscle is less than the length of the needle (A3). Lifting a skin-fold at the abdomen and thigh is relatively easier than in the buttocks and is virtually impossible in the arm. Ideally, the thumb and index finger are used to lift a skin-fold properly (possibly with the addition of the middle finger).^[14] Use of the whole hand while lifting the skin risks lifting muscle and can lead to

intramuscular injections.^[33] Use of skin-fold avoids soft-tissue compression and prevents the penetration of drug to a level deeper than intended.

Systematic rotation of injection sites

Systematic rotation of the injection sites is important as it:

- Helps maintain healthy injection sites
- Optimizes insulin absorption
- Reduces the risk of lipohypertrophy.

Organizing a site rotation scheme

Definition

Correct site rotation is defined as administering insulin injections using a new injection site for each injection, in a systematic manner, to avoid repeated local tissue damage, while ensuring stable insulin absorption by:

- Rotating between injection sites
- Rotating within injection sites, at least 1 cm apart
- Changing injection sites.

A common and effective scheme is to divide the injection site into quadrants (abdomen) or halves (thighs, buttocks and arms). One quadrant or half should be used for 1 week and then move either in a clockwise or an anticlockwise fashion to another quadrant or half, next week^[34] (A3). Proper and consistent rotation of injection sites safeguards normal subcutaneous tissue.^[14]

Injection technique

Syringe and vial

A syringe is the primary injecting device commonly used in India.^[7] While injecting insulin, one should confirm that the insulin is at room temperature; it should be taken out of refrigerator 30 min prior to injection. Before use, insulin bottle should always be inspected for expiry date, possible damage to the bottle and possible spoilage of insulin.

For steps of injecting insulin with a syringe, please refer to:

Kalra S, Balhara YS, Baruah MP, Chadha M, Chandalia HB, Chowdhury S, *et al.* First injection technique recommendations for patients with diabetes, FITs India. *Indian J Endocr Metab* 2012;16:876-85.

Mixing insulins

For a mixed dose, care should be taken to follow the right sequence of mixing. Regular insulin should be filled first followed by neutral protamine hagedorn (NPH) insulin. Reversal of this order can contaminate the regular insulin vials:

- Steps 1–12 would be similar for this too. However, care should be taken while mixing the insulins

- One must ensure that the right number of insulin units has been drawn as the insulin cannot be pushed back into the vial.^[35]

For steps of injecting insulin with a syringe, please refer to:

Kalra S, Balhara YS, Baruah MP, Chadha M, Chandalia HB, Chowdhury S, *et al.* First injection technique recommendations for patients with diabetes, FITs India. *Indian J Endocr Metab* 2012 Nov; 16:876-85.

Mixing insulins recommendations

Although a wide range of premixed insulin preparations is available, preparing split-mix insulin, by mixing rapid- or short- and intermediate- or long-acting insulin, may be necessary at times. Admixture of such combinations is needed in some patients to maintain euglycemia. The formulations and particle size distribution of insulin preparations vary, and on mixing, physicochemical changes may occur in the mixture either immediately or over time. This may result in variations in physiological responses to admixtures of insulin as compared to both component insulins being injected separately.

- Human short-acting (regular) insulin can be mixed with intermediate-acting insulin (NPH) in the same syringe in any ratio as desired^[36]
- When rapid-acting (lispro, aspart, and glulisine) and NPH are mixed, a slight decrease is seen in the absorption rate, but not in the total bioavailability. However, in clinical trials, postprandial blood glucose response was similar with this combination^[22]
- It is advised not to mix glargine (which has an acidic pH) with any other insulin; the time/action profile of glargine may change and precipitation of the preparation may occur^[37] (A2).

Pens

The method of device preparation is the same for both reusable and prefilled disposable pens. In the case premixed insulin is being used, one should ensure that the insulin has been re-suspended by rolling the pen. The edge of the pen should be cleaned with a swab, and a new pen needle screwed on. Insulin pen should be primed with two units of insulin as the first step. It should then be discarded, and the actual dose should be dialed in. The appropriate dose dialed can be seen on the device's display window and can be heard as audible clicks in many pen devices.^[38]

The selected injection site should be cleaned with an alcohol swab by starting in the middle of the area and then

moving in a circular motion outwards. Stinging may be reduced by ensuring that alcohol on the skin is completely dry before injection.^[39] The needle should be inserted in the skin and injection button pushed to deliver the insulin dose. Waiting for a while, by counting till 10, before withdrawing the needle, is advised to deliver the full dose and prevent leakage of the medication (A1). A longer waiting period may be required for higher doses.

The pen needle should then be removed from the pen and disposed safely.^[14] It is advised to release the pinch up only after the needle is taken out of the injection site. It is advised to remove and dispose the needle immediately after injection, instead of being left attached to the pen. This will prevent the entry of the air into the cartridge as well as leakage of the medication, which can affect subsequent dose accuracy (A2).

Injection-meal time gap

The efficacy of insulin may be affected by the time gap between injection and meal. Hence, the timing of injection with respect to meal is critical in controlling glycemic levels.^[40] Patients should always follow physician's advice.

Short- and rapid-acting insulins

Ideally, human short-acting (regular) insulin should be administered 30 min before meal as it has a delayed onset;^[40] whereas rapid-acting insulins (lispro, aspart, and glulisine) can be injected before or immediately after a meal.^[41] The efficacy of insulin may be accentuated or reduced by altering the time gap between insulin injection and meal, hence modulating the glucose-lowering effect. Such a strategy should be practiced only under a physician's guidance.

Intermediate- and long-acting insulins

Intermediate-NPH and long-acting insulins (detemir and glargine) should be injected at the same time every day but need not be related to meal times. The ultra-long-acting insulin degludec can be injected at any time, without regard to timing of meals or timing of the previous day's injections.

Glucagon-like peptide-1 receptor agonists

Various glucagon-like peptide-1 receptor agonists are now available, which are administered by different injection techniques. Exenatide is administered twice-daily, 30 min before meals. Liraglutide is injected once daily, without regard to meal timings. Some physicians advise liraglutide at bedtime to reduce gastrointestinal discomfort. Long-acting release exenatide is injected with a 23 gauge needle, once a week, at any time of the day. Dulaglutide and albiglutide are also injected once a week with 29 gauge needle.

Troubleshooting

Pain

Patient adherence to insulin therapy is often affected by the pain following an injection. Pain due to insulin injection is infrequent, unless the needle irritates the nerve endings. Good injection practices can minimize or avoid injection-associated pain [Table 3].^[14,42]

Local site reaction to subcutaneous insulin injection

- Lipodystrophy
- Lipohypertrophy: A thick soft to firm swelling with "rubbery" consistency
- Lipoatrophy/Lipodystrophy: A scarring lesion with depression
- Amyloidosis
- Bruising and bleeding.

Lipohypertrophy

Lipohypertrophy, often caused by repeated reuse of needles, manifests as a localized lesion at the repeated injection site [Table 4].

Chronic reuse of needles and injections at the same site may result in localized lipohypertrophy, or degeneration and atrophy. Patients tend to inject frequently in the lipohypertrophic sites because of reduced pain sensation. Injecting into lipohypertrophic sites may result in significantly unpredictable and delayed absorption which

Table 3: Minimizing pain associated with insulins

Preinjection	Appropriate messaging: Convey the benefits of insulin in a positive manner
	Appropriate site selection and preparation
	Appropriate device selection
	Thin gauge needles
	Short needles
	Pens requiring less pressure
	New needle for each injection
	Appropriate dose selection: Consider splitting doses in persons with high insulin requirement
	Appropriate insulin selection
	Consider U-100 insulin in persons with high insulin requirement
	Consider insulins with neutral pH if patients complain of pain with acidic pH insulins
During injections	Allow insulin to reach room temperature before injecting
	Allow the alcohol to dry before injecting insulin
	Do not raise a tight, blanched, or painful skin fold
	Inject slowly
	Avoid injecting at hair roots
	Avoid intramuscular and intradermal injections
	Avoid injecting over bruised or traumatized sites
	Do not move the needle while injecting
Postinjection	Follow a systematic rotation policy
	Release skin fold (if raised earlier) slowly
	Do not massage the injection site
	Feel happy; insulin is a life-saver

Table 4: Lipohypertrophy

Definition
A thickened, soft, firm, "rubbery" swelling
Prevalence
High
Diagnosis: By inspection and palpation
Raised swelling
Swelling which cannot be pinched together
Etiology
Repeated trauma to the same site (non-rotation)
Repeated use of the same needle (non-change)
Insulin per se: Anabolic effect
Associated factors
High daily insulin requirement
Frequent insulin injections
Basal-bolus therapy
Clinical relevance
Reduced absorption of insulin ^[45]
Erratic absorption of insulin-high glycemic variability ^[45]
Sudden reduction in insulin requirement when injections are administered at normal sites
Prevention/management
Regular inspection and palpation of insulin sites ^[45]
Do not reuse needles ^[45]
Follow correct site rotation policy ^[45]
Use larger injection surface areas
Do not inject into lipohypertrophy sites
Reduce the dose of insulin in habitual lipohypertrophy site injections when shifting to normal SC tissue
Rule out lipohypertrophy as a cause of poor glycemic control, hypoglycemia and high glycemic variability

can lead to hyperglycemia and/or hypoglycemia. Further, unnecessarily larger doses may be used in such cases.^[14,43] Thus, in patients with uncontrolled diabetes, the sites of insulin injection should be inspected and palpated before making significant changes to the dose or type of insulin.

A study showed that combined intervention of injection technique and injection site assessment by trained HCP followed by general and individualized injection technique education to avoid lipohypertrophy and use correct rotation along with switch to 4 mm needles lead to:

- Almost 0.6% (0.58%) mean fall in hemoglobin A1c (Hb1Ac) in 3 months
- Mean fall in fasting plasma glucose of 14 mg/dL
- Reduced insulin daily dose of 2 units.

These results are highly significant to patients and clinicians as the correct insulin technique can:

- Reduce the risk of complications significantly
- Support well-being and satisfaction of the patient
- Support treat to target Hb1Ac while minimizing need for additional insulin.^[12]

Bleeding and bruising

Occasional bleeding or bruising may occur due to reuse of needles. Clinical studies have reported that shorter

needles are associated with less frequent bleeding and bruising incidents. Bleeding and bruising appear to have no adverse clinical consequences for the absorption or action of injectable therapies.^[14]

Amyloidosis

Amyloidosis is a systemic or local disease in which amyloid substances are deposited extracellularly and impair tissue function.^[44] It has been shown that local amyloid deposition very infrequently takes place at the site of repeated insulin injection in patients with insulin-requiring diabetes.^[45-47]

The nature of amyloid in the insulin injection site is considered to be insulin itself or insulin-related substance and has been identified as amyloid insulin type (A Ins).^[46-50]

Blood glucose control improves markedly shortly after resection of the tumor or after the change of the injection site. The presence of the amyloid mass itself, perhaps due to poor penetration of insulin, may contribute to insulin resistance.^[51]

Trypanophobia (Belonephobia)

The fear of self-injecting insulin compromises glycemic control and emotional well-being. Similarly, the fear of pricking can be a source of distress and may seriously hamper self-management. Needle phobia may be associated with factors like a perceived loss of control over life, a lack of confidence that the demands of insulin therapy will be handled, a belief that insulin therapy equates to a personal failure and injection-related anxiety.^[11,14]

Needle-stick injuries

Needle-stick injuries commonly occur while recapping needles. Safety needles effectively protect health professionals against contaminated needle-stick injuries. Education and training are needed to ensure that safety practices are followed.^[14]

Injection through clothing

Injection through clothing is a common practice among patients, especially when in a hurry, or in a public place. This practice should, however, be firmly discouraged.

Needle/syringe hygiene

The United States Food and Drug Administration recommends injection needles for a single use only. Syringes should ideally be used only once. On the contrary, in India, patients often reuse syringes and needles for economic reasons. It is advised to counsel such patients about the potential hazards of reuse while explaining the technique of single-handed scoop recapping the needle cover aseptically after each use (although

against National AIDS Control Organization [NACO recommendations].^[52] The importance of not sharing syringes between individuals should also be emphasized. HCPs should adopt a pragmatic approach on this issue.

Following aspects of reusing the needles should be discussed with patients:

- When reusing, the thin tip of the needles gets damaged, needles bend, and the silicone lubricant coating of the needles is also lost. All these contribute to a more painful injection, with bleeding and bruising. Repeat usage can also result in breaking off and lodging of the needles under the skin. Furthermore, there is a higher chance for insulin to get deposited within the needle with reuse, making it harder to press on the plunger and deliver proper insulin doses
- Reuse of needles increases the risk of contamination and infection. In an attempt to be hygienic, some patients clean the needle with alcohol prior to reusing it. This practice removes the silicone lubricant and results in a more painful injection. This practice should be discouraged
- Repeated use of insulin needles can also result in damage to the tissues and an increased risk of lipohypertrophy^[45]
- Insulin pen delivery systems, when used properly, are extremely accurate. Improper use of pens with needles left attached after use bears more chance for the air to pass into the insulin chamber and an increased risk of contamination. Furthermore, there is a higher chance for dosage inaccuracy due to the air bubble formation. Hence, manufacturers recommend removing insulin pen needles immediately after use.

Periodic clinical audits

A periodic audit of injection practices in diabetes patients by their clinicians is highly recommended. Mutual audits can be performed in pairs by members of diabetes clubs or patient organizations.

Injection device disposal

According to the recommendations developed by NACO, it is recommended to collect the used needles or syringes in a puncture-proof box or safety box, labeled as "biohazard." When filled, these boxes should be handed over to appropriate centers such as waste management agencies, medical colleges, or hospitals, wherein disinfection and disposal of sharps are carried out.^[53] Needle clipping devices that remove insulin syringe needle and pen needles safely and easily, should be used.^[54]

Many people in India do not have access to sharps disposal devices. An easy and practical method is to collect

used sharps, including needles and lancets, in a strong cardboard/glass container, label and seal it, when full, and dispose it off at the nearest healthcare facility. Public facilities should be encouraged to provide sharps disposal devices in restrooms and retiring areas.

Missing injections

Insulin injections may be missed by patients either by design or because of unavoidable circumstances. All patients should be counseled about the negative effects of missing injections (A2). If a patient is admitted in the hospital and there is uncertainty about his current insulin regimen, human insulin should be administered until further information is available. This should always be done under medical supervision.^[22]

Special populations

Pregnancy

Insulin is required in about 10–20% of all antenatal women with diabetes, which complicates about one-sixth of all pregnancies. Patients should be reassured that insulin is not only safe in pregnancy, but also contributes to maternal and fetal well-being. The abdomen is a safe site for insulin administration in pregnancy.

First trimester

Women should be reassured that no change in insulin site or technique is needed.

Second trimester

Lateral parts of the abdomen can be used to inject insulin, staying away from the skin overlying the fetus.

Third trimester

Insulin can be injected over the abdomen while ensuring the skin fold is properly raised. Apprehensive patients may use the thigh or upper arm to inject themselves.

Dermatological disease

Insulin injection should be avoided at sites of active or recently healed infection or inflammations, such as skin and soft-tissue infections and psoriasis. Injection should not be administered into keloids or scars. However, stable vitiligo is not a contraindication for insulin injection. Acanthosis nigricans is also not a contraindication.

Surgical diseases

In patients with recent surgical wounds or open fistulas/ileostomies/colostomies, a different quadrant of the abdomen, should be used for insulin injection. Adequate preinjection cleansing must be done. Apprehensive patients with recent abdominal surgery may use thigh or upper arm for injection.

Elderly

It is recommended that elderly patients should be assisted by a caregiver and the importance of injection therapy, as well as prevention and treatment of hypoglycemia should be emphasized.

Sensory motor impairment: Visual, tactile and lack of manual dexterity

In visually impaired patients, nonvisual insulin measurement devices, syringe magnifiers, needle gauges, and vial stabilizers help ensure accuracy and aid in insulin delivery. In patients with both visual and dexterity impairment, prefilled syringes may be helpful (A2). Pens, which require low pressure for plunging, should be preferred.

In patients with low hearing and those who use hearing aids, therapy-related discussions should be conducted in a noise-free environment (A2). The instructor should face the person with sufficient light falling on his/her face which facilitates lip-reading. In addition, speaking slowly and clearly with normal intonation will also be a benefit. In people with dexterity problems, use of injection devices with preset doses and easy featuring devices may be beneficial.

Immunocompromised individuals

Hypoglycemia is a major concern in some immunocompromised patients, including those with HIV and hepatitis.^[55] Hence, early initiation of insulin therapy should be considered in immunocompromised patients as it improves therapeutic outcomes.^[55] Personnel giving injections and those handling the sharp material are at high risk of exposure and transmission of blood-borne pathogens (HIV and hepatitis) through injections and finger sticks administered to affected patients.^[56] Therefore, needles, syringes or lancets should never be reused (A2).

Insulin pump infusion

The insulin pump is a pager-sized device, which provides continuous subcutaneous delivery of rapid-acting insulin with the help of an infusion set. One end of the infusion set connects to the reservoir, which is filled with insulin and is kept inside the insulin pump, and the other end of the infusion set is connected to the needle placed subcutaneously.^[57]

In India, unlike in the Western world, pumps are more commonly used in type 2 diabetes. As an alternative delivery system, insulin pumps are a replacement for syringes/pens, provided the subject fulfills the essential criteria for a pump candidature. Since there are no reimbursement policies for pump users in India, most of the subjects have innovated and improvised their own ways and means of reducing the cost by prolonging the use of infusion sets and reusing reservoirs.

Such peculiar circumstances have created an urgent need for formulating insulin pump infusion recommendations. These need to be customized for the Indian subcontinent, considering education, ethnicity, dressing styles, resources, and weather, while at the same time ensuring clinical efficacy and avoidance of infections.

Infusion site

The preferred infusion site for pumps is the abdomen, while the upper arm and thighs are alternate sites. Select a site in the abdomen 5 cm away from the umbilicus and every new site should be 2.5 cm away from the previous site. Following a systematic pattern will help ensure that the longest possible time will pass before using the same site again. In pregnancy, the outer thigh or hip may be used.

Cannula selection

Plastic cannulae are preferred by almost all doctors recommending an insulin pump. Steel needle infusion sets are recommended in pregnancy, for patients who have reactions to plastic cannulae and who have frequent kinks in plastic cannulae. Short length cannulae (6 mm for 90° sets, 13 mm for 30–45° angled infusion sets) are most preferred. Shorter tubing is recommended for most patients while longer tubing is preferred by patients who feel comfortable keeping the pump in the socks or underneath the pillow while sleeping.

Angle of insertion

Insertion angle 90° is widely used by pump users. 30–45° angles are preferred by dexterous lean or muscular patients and pregnant women.

Selection of infusion sets

The most popular infusion set is a 90°, soft cannula infusion set. Variable angle, soft cannula infusion sets are also available for patients who are lean or lead an active lifestyle. Steel needle infusion sets and 90°, soft cannula infusion sets that combine the infusion set and insertion device into one unit are also available.

Troubleshooting

Adhesive tape allergy

This is extremely rare in Indian scenario, and the use of oral antihistaminics for a few days usually suffices.

Infusion site infection prophylaxis

The infusion site must be clean and dry before insertion of the cannula. Washing the site with an anti-bacterial soap or solution is sufficient. Changing the infusion set once in every 2–3 days is recommended. In India, most of the pump users retain the same infusion set for 5–7 days due to the high cost of consumables.^[58] With this practice,

the potency of insulin will be lost; there are chances of the site getting infected as well. Customized advice and recommendations are to be made based on affordability, work pattern, and level of education.

Lipohypertrophy

Lipohypertrophy has been described in the earlier part of the recommendations.

Loss of insulin potency

If patients use the same reservoir and insulin for more than the recommended 3 days, the potency of insulin may be compromised. If patients fill the reservoir with fresh insulin without changing the infusion set, adequate instructions have to be given by the diabetes care team. For subjects living in extremely hot environments, pump may not be a suitable option.

Pump occlusion

The newer cannula rarely kink and block. If the occlusion persists, the cannula and infusion set have to be changed.^[59,60]

Disaster management

Avoiding or missing insulin therapy in persons with type 1 diabetes can be life-threatening. Hence, disaster planning is essential and should include the precautionary steps to be taken if a disaster strikes. A portable, insulated, and waterproof diabetes disaster kit should be kept handy. The kit should have a supply of insulin syringes for at least 30 days and insulin vials or pens and needles along with cold packs. In addition, it should also contain blood-testing supplies including lancets, test strips, and a glucose meter (preferably two) with extra batteries. A separate sharps container for the disposal of lancets and needles should also be included.

At least a 3-day supply of nonperishable food and bottled water is also recommended.^[11]

Barriers to insulin therapy

Patient-related barriers

Several myths, misunderstandings, and negative approaches act as barriers in the use of insulin among type 2 diabetes patients.^[9]

- Clinicians may help patients discuss their concerns by asking open-ended and nonjudgmental questions: Effective solutions can thus be found and implemented
- Encouraging shared decision-making with active participation of the patient is important
- Giving patients a sense of control over their treatment plan improves acceptance and enhances adherence.

Physician-related barriers

- Physicians are often concerned about the patient-related barriers in early initiation of insulin therapy
- Physician-related barriers include concerns about adherence and the patient's perceived adverse effects of hypoglycemia and weight gain, lack of supporting staff and counseling/motivational skills, and the desire to prolong noninsulin therapy
- Physicians have a misconception that insulin therapy is expensive; however, insulin therapy actually reduces costs by decreasing complication rates and management burden.

Health care system-related barriers

- Lack of resources also acts as an important barrier in insulin therapy. A financial barrier exists for patients who lack insurance
- For HCPs, lack of trained diabetes educators is an important issue
- This can be linked to the lack of resources, ability, and/or facilities for training diabetes educators
- Use of reusable insulin pens; providing training to HCPs; and hiring a diabetic educator and setting up an educational program may be helpful in increasing the availability and lowering the cost of insulin therapy.^[54]

Improving adherence

Counseling forms an integral part of diabetes management. Counseling about drug-, patient-, and physician-related factors can improve adherence to injection therapy. These factors are listed in Box 6.21.

Encouraging patients to ask questions and clarify doubts is important. Arranging periodic refresher sessions with patients is helpful in addressing any new issues that arise during the course of therapy.^[61] The message should be personalized, and information relevant to the patient's perspective should be provided.^[62]

The WATER approach explained below has been suggested to fulfill the purpose [Table 4].

- The patient must be Welcomed Warmly in the clinic, from the outpatient counter onwards
- The clinicians should Ask and Assess carefully making use of various cues and sequencing the questions appropriately
- They should tell truthfully making use of metaphors analogies, keeping in mind both verbal, as well as nonverbal cues from the patient
- They should explain with empathy, making use of experience sharing, practical demonstration, and

- imparting coping skills training
- Finally, the clinicians must reassure the patient and tell him/her to Return for any clarifications^[63]
- Optimization of insulin-related and device-related factors can help improve adherence to insulin therapy.

CONCLUSION

The FIT India recommendations 2015 have been designed to address the needs of people with diabetes and HCPs in India. Their relevance, however, is global that is, global as well as local. These recommendations provide a reader-friendly, yet comprehensive, source of information for all stakeholders connected with injectable therapy for diabetes. It is hoped that the FIT India recommendations will contribute to improved glycemic control in people with diabetes, in India, and across the world.

DUALITY OF INTEREST

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Mr. K Sudeep	Mangalore	Dr. Sharma DC	Udaipur
Dr. Kalra Bharti	Karnal	Dr. Sharma SK	Jaipur
Dr. Kanungo Alok	Bhubaneshwar	Dr. Sethi Bipin	Hyderabad
Dr. Kapoor Rohit	Amritsar	Ms. Shetty Zankhana	Mumbai
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Dr. Makkar BM	Delhi	Dr. Jawad Fatema	Pakistan
Dr. Mallya Ganapathi B	Bangalore	Dr. Mohsin Fauzia	Bangladesh
Dr. Manjunath Ramakrishnaih	Bangalore	Dr. Osama	Pakistan
Ms. Mehta Rutu	Mumbai	Dr. Raza Syed Abbas	Pakistan
Dr. Mehta Shalmi	Ahmedabad	Dr. Somasundaram Noel	Sri Lanka