The Safety of Injecting Insulin Through Clothing

DORIS R. FLEMING, MSN, RN, CS, CDE
SCOTT J. JACOBER, DO, CDE
MELISSA A. VANDENBERG, BSN, RN, CDE
JAMES T. FITZGERALD, PHD
GEORGE GRUNBERGER, MD

OBJECTIVE — Many of the "antiseptic" practices recommended by health care professionals for insulin injection have been successfully challenged as unnecessary. Since people with diabetes have long been observed to inject their insulin through their clothing, this study was undertaken to determine the safety and perceived benefits of administering insulin by this "rogue" technique.

RESEARCH DESIGN AND METHODS — Fifty people with insulin-treated diabetes were randomized into a 20-week single-blinded prospective crossover study comparing the conventional subcutaneous injection technique (with skin preparation) to an experimental injection technique through clothing. Skin assessment, glycated hemoglobin levels, and leukocyte count were determined before randomization, at 10 weeks (before crossover), and again at 20 weeks (at completion). The participants injected through a single layer of fabric, which ranged from nylon to denim. Problems, benefits, type of clothing, and other comments were recorded by the subjects in an injection log.

RESULTS — Forty-two (84%) subjects completed the study. The mean age was 41 years (range, 23–63 years), 50% were women, 86% were Caucasian, and 80% had type I diabetes. The mean duration of diabetes was 14 years (range, 1–33 years). Fifty-one percent had >16 years of education. The demographic characteristics of the dropouts were similar to those who completed the study. Over the 20-week period ~13,720 injections were performed by participants. None of the subjects experienced erythema, induration, or abscess at injection sites. Neither the glycated hemoglobin levels nor the leukocyte counts differed between the conventional and experimental regimens. During the injection-through-clothing phase of the study, only minor problems, such as blood stains on clothing and bruising, were recorded in the logbooks. However, subjects reported that injection through clothing offered benefits such as convenience and saving time.

CONCLUSIONS — It is safe and convenient to inject insulin through clothing.

Present recommendations for insulin injections are complicated, time consuming, and inconvenient. Practices such as swabbing the skin with alcohol (2–4), aspiration for blood (5), mixing long- or intermediate-acting insulin by rolling the vial (6), the single use of disposable needles (7–21), piercing the skin at a 45° angle regardless of the patient's size (5), and rotating the site of injections in a clockwise fashion (22) were never validated in controlled studies before their implementation and have been challenged. Fifty years ago, insulin injection emphasized "sterilization" techniques (1); however, the "antiseptic" utility of quickly swabbing the injection site with alcohol has been refuted (23–33). The current American Diabetes Association position statement on insulin administration neither directly advocates nor condemns the use of alcohol skin preparation but only recommends that alcohol, if used, be allowed to evaporate before injection (34).

From the Diabetes Program (D.R.F., S.J.J., M.A.V., G.G.), Division of Endocrinology, Metabolism, and Hypertension, Department of Internal Medicine, Wayne State University School of Medicine, Detroit, Michigan; and the Department of Postgraduate Medicine (J.T.F.), University of Michigan, Ann Arbor, Michigan.

Address correspondence and reprint requests to Doris R. Fleming, MSN, RN, CS, CDE, Diabetes Program, 4201 St. Antoine, UHC-4H, Detroit, MI 48201.

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CBC, complete blood count; MANOVA, multiple analysis of variance; WBC, white blood cell.

If antiseptic skin preparation other than for reasonable cleanliness is unnecessary, could other injection procedures be eliminated without increased adverse effects? Clearly, not having to swab the skin with antiseptic makes the injection process less time-consuming. Eliminating the exposure of bare skin for injection makes partial disrobing and the need for privacy both unnecessary and thus provides greater convenience. Furthermore, when outside of the home, an appropriate place to undress and inject is often difficult to locate and is frequently an objectionable (and less than hygienic) public toilet. This study was prompted by the unsettled reaction of one of the investigators (D.R.F.) to the observation of a colleague (S.J.J.) publicly injecting insulin through clothing; similar anecdotes have long circulated among health professionals since Dr. Charles Best who spoke of the English diabetologist R.D. Lawrence injecting insulin through his clothing in the 1930s to "entertain his professional friends" (John K. Davidson, personal communication).

Before this prospective study, we undertook a retrospective survey to assess the experiences of individuals who had practiced this technique contrary to medical advice. We identified by word of mouth 21 people aged 18–82 years (mean, 40.6 years), 10 of whom were women. These people had been using this technique from 6 months to 59 years (mean, 8.1 years). Most were health care providers, but other occupations were represented (receptionist, attorney, truck driver, and salesman). Twenty had type I diabetes (duration of diabetes, 3–64 years; mean duration, 19.0 years). All but four individuals took insulin 3–6 times per day (range, 1–6 times/day; mean, 3.2 times/day) with a frequency of injections through clothing ranging from every injection to 2–4 times a month. The total number of injections through clothing was estimated to be 66,807 over 170 patient-years. Injecting insulin through clothing was done for convenience either at work or in social settings. A truck driver who had been injecting through clothing for 59 years did so even while driving. No participant in this survey ever reported any infection of an injection

site. The only problems reported were bruising and minor bleeding at the injection site with staining of the clothing, neither of which deterred individuals from continuing this practice.

RESEARCH DESIGN AND METHODS

— This study was a 20-week single-blinded prospective cross-over trial comparing conventional subcutaneous insulin syringe-injection practice (with skin preparation) to an experimental subcutaneous insulin syringe-injection practice (through clothing). Subjects with either type I or type II diabetes who had been injecting insulin for ≥1 years were recruited from patients of the Wayne State University Diabetes Clinics during a 12-month period in 1994–1995. Fifty subjects were enrolled after providing an informed consent approved by Wayne State University Human Investigation Committee.

At enrollment, a history and physical examination were performed on subjects with an emphasis on skin assessment to identify any preexisting skin problems. Blood samples for a complete blood cell (CBC) count with differential, chemistry panel, and glycated hemoglobin were obtained. Participants were randomized into one of two treatment groups. Subjects randomized to group A injected insulin through clothing for 10 weeks followed by 10 weeks of the conventional technique. Those individuals randomized to group B injected insulin by the conventional technique for first 10 weeks followed by the experimental technique for 10 weeks.

All subjects were instructed to use only their thighs for injections. During the conventional injection technique interval, subjects were to wipe their skin on either thigh with alcohol, allow it to dry, and then inject the insulin. During the experimental phase, the subjects were to inject the insulin into either thigh and through only one layer of fabric. Individuals on multiple injections were instructed to administer at least one injection per day through clothing during the experimental phase and had the option of injecting more or all of their injections through their clothing. Subjects received a written list of fabric options that included cotton, polyester, wool, denim, silk, nylon, Lycra, rayon, flannel, linen, and blends of the above. Participants were not given any specific instructions regarding the rotation of injection sites other than limiting the sites to the thighs. Subjects were educated regarding the signs and symptoms of infection and were told to inspect their thighs daily and to notify the investigators immediately if they suspected any infection.

After 10 weeks, subjects who completed both the conventional and experimental injection technique had their thighs reexamined. A CBC with differential and glycated hemoglobin measurement was repeated. For the final 10 weeks of the study, subjects crossed over to the opposite treatment group. All participants were re-instructed on injection techniques and reminded to record injections in the daily logs.

At completion of the second 10 week interval, the subjects underwent a final skin assessment and measurement of a CBC with differential and glycated hemoglobin. All weekly injection logs were collected at this time. These logs were not reviewed by the investigators until all subjects completed the study.

Total glycated hemoglobin was measured by an affinity chromatography technique (Glycaffin, Isolabs, Akron, OH) with a normal range of 4–8% (mean, 6%, SD 1%).

Differences between the conventional and experimental groups for the white blood cell (WBC) count, the differential counts, and the glycated hemoglobin levels were determined by multiple analysis of variance (MANOVA) with repeated measures.

All participants received weekly log sheets with both verbal and written instructions to record the date, time of injections, whether or not the injection was by the conventional method or through clothing, benefits, problems, type of clothing during the experimental phase, and other pertinent comments. Subjects were given codes to record in their logs for the following benefits: "saves time," "convenient," "less noticeable," and "less awareness." Similarly, they were provided with codes for the following problems: "blood," "bruising," "pain," and "infection." In addition, subjects were encouraged to write open-ended comments on their logs.

In spite of verbal and written instructions related to the completion of the weekly log, subjects recorded data in a variety of ways. Some participants recorded information for every injection every day, while others recorded information only once a week. To avoid over-representation of entries from a specific phase of the study, the logbook entries were analyzed for only the first and last weeks of each 10-week period (i.e., weeks 1, 10, 11, and 20). Both the benefits and the problems of the two injection methods were analyzed. If a benefit type (e.g., "saves time") or a problem type (e.g., "blood") was recorded at least once during an entry day, it received a score of 1 for that day (the maximum number of benefits or problems for an entry day was 4). The average number of benefits per day was determined by dividing the total number of benefits recorded by the number of days entries were made (e.g., if a subject had 5 days of entries and reported "saves time" on 3 days and "convenient" on 2 days, his or her average benefit per day was [3 + 2] / 5 = 1). The same procedure was used to determine the average number of problems per day.

The logbook entries of the conventional method phase (weeks 11 and 20 for group A and weeks 1 and 10 for group B), and the experimental injection method phase (weeks 1 and 10 for group A and weeks 11 and 20 for group B) were initially compared using MANOVA with repeated measures. After establishing that the entries for each group within a phase were not statistically different, the data were collapsed and comparisons made between the two injection methods using paired *t* tests.

RESULTS

Demographic characteristics

Forty-two (84%) of the enrolled subjects completed the study. The demographic characteristics of those who completed the study did not differ from those who dropped out. Fifty percent of those who completed the study were women. The mean age was 41 ± 11 years (range, 23–63 years). Twelve percent were self-described as African-American and 86% were Caucasian. Subjects were highly educated, with 50% having attended ≥16 years of formal schooling and only 21% had ≤12 years. The mean duration of diabetes was 14 ± 8 years (range, 1–33 years), and 78% had type I diabetes. Twelve percent used one insulin injection per day, 57% used two, 19% used three, and 12% used four. Subjects made a total of 7,275 injections through clothing during 3,339 patient-days.

Laboratory results

Table 1 shows the laboratory results. No significant differences were found between the results of patients in the two groups or within each group.

Skin assessment

No enrolled subject contacted the investi-

Table 1—*Laboratory measurements*

	n	Baseline	10 weeks	20 weeks	*P* value
WBC (10^3 cells/μl)					
Group A	24	6.30 ± 1.91	6.40 ± 2.09	6.07 ± 1.82	0.30
Group B	14	6.81 ± 2.90	6.74 ± 3.20	7.09 ± 2.98	
Neutrophil (%)					
Group A	24	59.50 ± 10.11	60.00 ± 10.45	57.79 ± 8.91	0.14
Group B	15	59.07 ± 7.85	59.67 ± 8.24	61.20 ± 5.66	
Glycated hemoglobin (%)					
Group A	24	10.73 ± 2.04	10.94 ± 2.45	10.61 ± 2.43	0.63
Group B	15	10.79 ± 2.54	11.39 ± 2.86	10.73 ± 2.87	

Data are *n*, means ± SD, or *P* determined by paired *t* test.

gators during the study to report any adverse skin reactions. No enrolled subject experienced or demonstrated on physical examination any erythema, induration, abscess, or rash of the thighs.

Log entries

Table 2 indicates the average of number of coded entries per day by injection technique. The results showed that the average number of recorded problems per technique per day did not differ between the two methods. However, the average number of recorded benefits during the experimental method was significantly greater than that during the conventional method.

As determined from the open-ended comments, subjects found the injection-through-clothing technique convenient when they were away from home, particularly at work and when eating in restaurants. Many individuals felt liberated from looking for restrooms and having to take their insulin in these "dirty" places. Others noted less constraint in rotating injection sites because all sites could be readily accessed through clothing as opposed to partial disrobing. Some subjects had difficulty injecting through thick cloth such as denim, while others noted small blood stains on clothing, but no difference in either bleeding or bruising was noted between methods.

CONCLUSIONS — The insulin treatment regimen for diabetes requires a complex set of self-care behaviors. Individuals using multidose insulin regimens are hampered not only by the increased frequency of performing these behaviors but also by the logistics of performing these tasks away from home. The transportation of equipment and medications and the need to find a private location to partially disrobe makes the regimen particularly obtrusive. Insulin injection through clothing decreases both the complexity and obtrusiveness by removing the need to first prepare bared skin. As a result, the injection technique is simplified, the number of injection supplies are reduced, and the logistics of securing a private location may be eliminated by a discreet injection in public. This study demonstrated that 7,275 injections through clothing were not associated with any clinical indication of infection at injection sites over 3,339 patient-days. There were also no differences in WBC or glycated hemoglobin values. Subjects reported significant benefits of the insulin-through-clothing technique and reported no differences in perceived problems between the conventional injection technique and the injection-through-clothing technique.

Although our present prospective study can only substantiate the lack of complications of injecting through clothing for 7,275 injections over 3,339 patient-days or 9.14 patient-years, our retrospective survey anecdotally corroborates this safety issue for a much longer period. Other studies have demonstrated similar safety concerns regarding the omission of routine cleansing of the skin with alcohol or reusing syringes with fewer injections over a similar study duration (2,4,10,17, 18,31).

The technique of injecting through clothing probably adds little risk beyond omitting alcohol-swabbed skin preparation. The necessity of skin preparation before insulin injections has been disputed for more than 30 years (33). Cleansing the skin with alcohol before injections is based on the belief that breaking the skin barrier would cause an entry point for bacteria to be carried into the tissues. However, several factors refute this assumption. There have been few incidences of infections reported, the number of bacteria carried through a small gauge needle used in injecting insulin is well below that needed for infection to occur, most insulin preparations have bacteriostatic additives that inhibit bacteria growth, and insulin injections are primarily done at home where there are few virulent organisms (2,21,24–26). Since 1962, skin preparation before smallpox vaccinations was discontinued in England by the health department as long as the skin was reasonably clean (35). Dann (3) has commented that "dentists for decades have been giving injections into the gums and soft tissues of the mouth without any attempt at sterilizing or cleaning the mucous membranes, and without any obvious harmful effect. The incidence of infections occurring after injections have usually been linked to contaminated syringes, needles, or solutions and not to prior skin preparation." Although we did not culture clothing, we speculate that relatively clean and dry clothing would provide little additional bacterial contamination than the skin itself. Like Dann, we also would like to consider the possibilities of bacterial contamination of injecting through the oral cavity compared with injecting through a woven layer of cloth.

Fewer than one third of patients actually incorporate into their daily routine all conventional insulin injection practices like

Table 2—*Logbook problems and benefits: conventional method versus experimental method* (n = 29)

Insulin injections	Number of entries per day	*P*
Problems with		
Injection with skin preparation	0.32 ± .33	0.19
Injection through clothing	0.40 ± 0.37	
Benefits with		
Injection with skin preparation	0	<0.01
Injection through clothing	1.34 ± 1.11	

Data are means ± SD or *P* determined by paired *t* test.

hand washing, vial preparation with alcohol, swabbing the skin with alcohol, and discarding disposable syringes after a single use (31). Health care practitioners know that patients do not always follow their advice, and this study was derived from the observations of "noncompliant" behaviors of some patients. This study underscores the need for health professionals to scrutinize patient behaviors with an open mind. This particular "rogue" practice offers little risk of complications and can simplify an already complex diabetes regimen. We conclude that insulin injection through clothing is safe and convenient.

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