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Palco Labs, Inc.
Final Results and Report

STUDY: INJECT-EASE USE WITH PATIENTS ON GROWTH HORMONE
THERAPY

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ABSTRACT

The purpose of this study was to determine if an inject aid device would reduce the fear and pain associated with injections in patients on growth hormone (GH) therapy. Twelve patients were randomly selected to receive the Inject-Ease device for use with the 3-6 required injections per week. Six patients were new to GH injections and four were currently taking GH injections. Both groups were instructed by the nurse educator on using the device. Two patients were instructed on manual injections at the initial visit and were mailed the Inject-Ease and asked to participate in the study by following the manufacturer's instructions. The patients were then asked for their opinion by means of a scaled questionnaire mailed to them after using the device for 3 months.

A strong preference for using the Inject-Ease, as opposed to manual injections, was indicated. All participants responding agreed that it was easy to use and that the patient could learn to use this device for self-injections. Even though only eight of twelve patients felt that the injections were less painful when using the device, all but one participant agreed that the Inject-Ease helped reduce the fear of injections.

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For the patient facing the prospect of growth hormone (GH) therapy, it can be frightening thinking of receiving injections 3-7 times a week for an indefinite period of time. The patient currently on GH therapy is continually searching for a way to improve his/her technique in order to decrease the pain and apprehension of the injection. There are several devices available which are designed to make frequent injections a more pleasant and less fearsome procedure. The manufacturers claim that these devices decrease the trauma and anxiety of injections and that injections are easier and more comfortable as a result of using these devices. The purpose of this study was to investigate these claims by applying the use of the Inject-Ease (Palco Laboratories) to a sampling of patients on GH injections from our practice.

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Patients seen for GH therapy in May - August 1988 were randomly selected and assigned to one of three groups. Group A consisted of six patients new to GH therapy with no previous experience giving injections. Group B was composed of four patients who were currently taking GH (6 months - 2.5 years duration) and who had no experience with inject aid devices. In Group C, two patients were instructed to do manual injections at the initial visit, then three months later were mailed an Inject-Ease and asked to begin using it for their GH injections by following the manufacturer's instructions. Groups A and B received instruction from the nurse educator on using the device, with Group A receiving the first injection by the nurse at the initial visit and Group B doing the first injection with the device at home. Patients ages ranged from 9 to 15 years, with a median age of 11 years, and all patients, with the exception of one from Group B, were on three injections per week at the beginning of the study.

A seven statement questionnaire was sent to each participant family after using the Inject-Ease for approximately three months. The patient/family was asked to rank the following statements according to the scale:

1 - strongly agree, 2 - agree, 3 - no opinion, 4 - disagree,
5 - strongly disagree.

- 1) The Inject-Ease was easy to use.
- 2) My child could learn to use this device to give his/her own growth hormone injections.
- 3) The written instructions enclosed in the Inject-Ease box were easy to understand.
- 4) Using the Inject-Ease helped to reduce the fear of injections.
- 5) The growth hormone injections using the Inject-Ease were less painful than injections without using the Inject-Ease.
- 6) We found the time spent using the Inject-Ease to be worth the extra effort to use it.
- 7) We plan to continue using, or resume using, the Inject-Ease device for growth hormone injections.

RESULTS

The overall results indicated a strong preference for using the Inject-Ease. All participants felt that it was easy to use and that the patient could learn to use this device to give his/her own GH injections. In fact, two patients began giving their own injections during the study period and three will not let the parents give the GH without the Inject-Ease device. 92% felt that the written instructions were easy to understand and that the time spent using the device was worth the extra effort. Eight patients felt that injections were less painful using the

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Inject-Ease. Two patients had no opinion and two felt that the injections with the device were just as painful as manual injections. Eleven of twelve patients felt that using the Inject-Ease helped to reduce the fear of injections and ten plan to continue using the device after the study.

In the patients who were new to GH therapy, only half felt that the injections were less painful using the device. However, of the patients who had been on GH therapy for 6 months to 2.5 years, 100% felt that using the device reduced the pain and fear of the injections. In the group who was mailed the Inject-Ease after beginning therapy with manual injections, one participant felt that using the device caused "too much of a surprise because" the patient "can't see the syringe". The other member of Group C has gone from 3 times per week injections to daily injections. The Inject-Ease was instrumental in the patients decision to go to multiple injections.

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DISCUSSION

By offering an alternative injection method to patients on GH therapy, we found that we were able to help them reduce some of the fear and pain associated with these injections. One patient in each group has gone to 6 or 7 injections per week with the aid of this device. One patient in particular has benefited greatly from using the Inject-Ease. The parent has a tremendous fear of injections and could not even watch the preparation of the injection. This parent is now giving the injections with the aid of the Inject-Ease.

The patient on growth hormone therapy has undergone a battery of tests and examinations to be able to receive this "miracle formula" which will help him/her grow to his/her potential. We are now asking this child to take injections for an indefinite period of time. This is a big decision for the parent and child, and we, as the health care team, should share any knowledge we have to make these injection times as comfortable and pleasant for the family as possible. An inject-aid device may not be the answer for every child, as we have seen; but, if it can reduce the trauma associated with injections, it is worth the time and effort we invest to educate that patient and family.

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