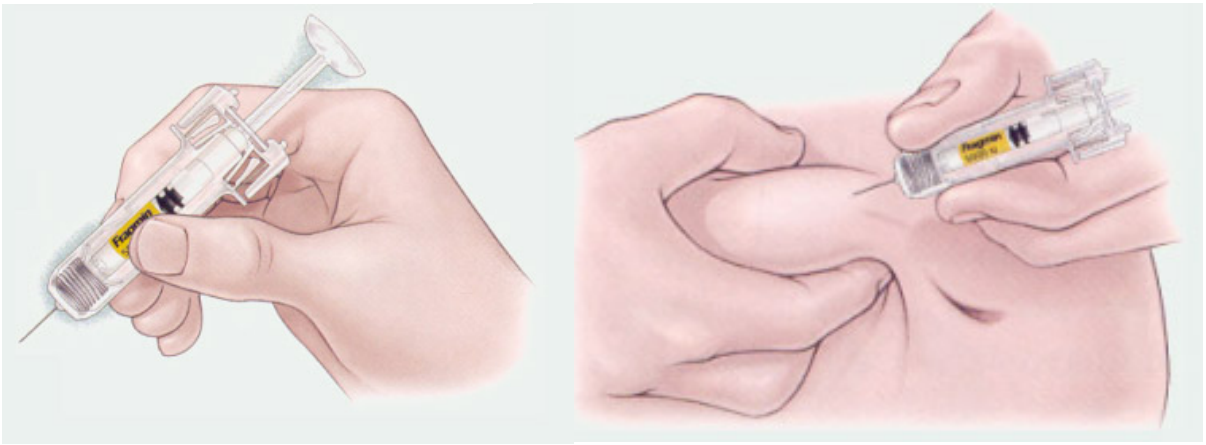
Selbstmanagement Heparintherapie

Compliance bei der Selbstinjektion von niedermolekularen Heparinen in der ambulanten Praxis

Entwicklung einer Pilotstudie



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Selbstmanagement Heparintherapie – Compliance bei der Selbstinjektion von niedermolekularen Heparinen in der ambulanten Praxis. Entwicklung einer Pilotstudie.

Abstract

Background

The daily subcutaneous injection of low molecular weight heparins (LMWH) is carried out frequently at home, independently by the patient or by a family member. Randomized controlled trials document that an ambulatory LMWH-therapy for selected patients is safe and efficient and is associated with a higher patient satisfaction and a reduction of costs. There is very little data available on application problems and on compliance with ambulant LMWH-therapy; furthermore its quality is moderate. But as a matter of fact compliance represents a significant problem and abandonment or interruption of the treatment is common. Against this background the project “Self-management of heparin therapy - compliance with self-injected low molecular weight heparin in ambulatory care” was generated. The project is divided into a pilot and a main study. The aim is to optimize the ambulatory care of patients with prescribed LMWH by the pharmacy. The hypothesis is: “Intensive pharmaceutical care provided to ambulatory patients who self-inject LMWH after discharge from hospital results in improved compliance, more safety and satisfaction as well as in fewer complications.” Within this extensive project the following aims were defined for the master thesis: Development of interventions and measuring instruments as well as planning and starting the pilot study.

In the **sub-project A** the measuring instruments, which are feasible for testing on healthy subjects, were validated.

Personal experiences and feedbacks from nursing staff indicate that problems in removing the protection cap from ready-prepared syringes are not unusual. In the **sub-project B** the handling of three different LMWH-brand products was compared. The hypothesis is: “Removing the protection caps from LMWH-brand products (Fragmin®, Fraxiparine®, Clexane®) costs the *same* effort from *all three* syringes.”

Patients and Methods

The study was an open, randomized controlled trial. The recruitment of patients with prescription for Fragmin® took place in the “musculoskeletal system treatment centre” from University Hospital of Basel and in the rehabilitation center from the “Felix Platter” Hospital in Basel. The participants were randomized to the intervention or control group. Immediately after hospital discharge a detailed instruction and consulting service were offered to the patients of the intervention group at the study center. Patients of the control group were discharged from hospital in a conventional manner and received standard care in the pharmacy of their choice. The data collection was recorded by structured, questionnaire based telephone interviews and by a monitored self-injection (direct observation technique). To present the analyses of the questionnaires, scores to subjective and objective appraisals were developed.

Sub-project A: Because the newly developed “direct observation technique” is one of the most important measuring instruments and because its results are based on the observation from examiners, it had to be validated in detail. 34 pharmacy students in the 5th study year were requested to carry out a subcutaneous injection with placebo-syringes. In the same time it was tested how extensive the knowledge of the students was after attending a half-day injection training course and if they felt confident with the injection technique, which is a condition for providing support to customers and for conducting an injection, if required.

Sub-project B: For the comparison of the syringes the following three frequently used LMWH-brand products Fragmin® (Pfizer), Fraxiparine® (GlaxoSmithKline) and Clexane® (Sanofi-aventis) were selected. The effort, which was needed to remove the protection cap from the syringe, was measured on a Visual Analogue Scale (VAS: 0mm = „huge effort“, 100mm = „no effort“) by the participants. Sub-project B was carried out on two different population groups: on healthy, young pharmacy students and on a representative population of patients and pharmacy customers (n_{tot} = 68).

Results

The recruitment of patients proved to be more challenging than expected. Until the end of the master thesis, four patients could be recruited in the pilot study. Despite the very small number of cases, it can be said, that the different procedures within the pilot study were planned in a manner so that a smooth implementing is ensured.

Sub-project A: Only 73.5% of the students dared to inject themselves. Out of these 25 students, only 3 (12.0%) felt “very confident” with the injection. 19 students (76.0%) felt “reasonably confident” and 3 (12.0%) even “rather unconfident“.

Sub-project B: Statistically highly significant differences of the mean values between Fragmin®, Fraxiparine® und Clexane® were observed: The protection cap of Fragmin® was the most easiest to be removed (mean of the VAS-values: 83.7±15.8mm), followed by Clexane® (59.3±27.8mm). The removal of the protection cap of Fraxiparine® needed the biggest effort (49.4±30.5mm). In spite of repeated attempts, a total of three participants (4.4%) were not able to remove the protection cap of Fraxiparine® and two (2.9%) the one of Clexane®.

Conclusions

The pilot study will be continued, evaluated and adapted for the following main study by Seraina Mengiardi within her dissertation. Due to the difficulties in recruiting patients, recruitment in other hospitals and extending the inclusion criteria are necessary to reach an adequate number of cases in the main study within a reasonable time.

Sub-project A: The intensity of the injection training course was *not* sufficient for *all* students to attain a satisfying level to apply an injection to a third person. The aim of the planned RCT is to improve the support of patients with prescribed heparin by the pharmacist. It needs to be evaluated, if such customer care may be offered by all or only specialized pharmacists.

Sub-project B:

The hypothesis “Removing the protection caps from LMWH-brand products costs the *same* effort from *all three* syringes” must be abandoned. Removing the protection caps from the syringes caused big difficulties. Failing right at the beginning of an injection reduces patient’s motivation and ability to correctly administer the therapy, which potentially results in unintentional non-compliance.