

The Safety and Efficacy of Continuous Heparin Infusion Therapy in the Home

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Abstract

Patients making the transition between oral anticoagulation with warfarin and parenteral treatment with heparin prior to and after surgery and/or a diagnostic procedure received continuous infusion of intravenous heparin in a home setting. The mean activated partial thromboplastin time for the heparin-treated cohort was 72.68 ± 37.4 seconds (range, 28 to 280 seconds). There were no bleeding or thrombotic complications. For patients making the transition from oral warfarin to heparin, the mean and standard deviation of the preprocedure prothrombin time was 13.36 ± 1.3 seconds (range, 11.5 to 15.4 seconds). For those making the transition from heparin to oral warfarin, the mean and standard deviation of the postprocedure prothrombin time at the completion of intravenous heparin was 17.9 ± 2.65 seconds (range, 13 to 21.1 seconds). Overall medical costs were reduced, with an average calculated cost saving per patient of \$4,788. Patient satisfaction was 98% after program completion. We conclude that continuous intravenous heparin can be administered safely in a home setting, with therapeutic efficacy, patient satisfaction, and reduced costs to the health-care system.

The shift in healthcare delivery sites from hospitals to alternative locations is a current reality. As a result of the availability of well-trained, highly skilled personnel, technological advances in delivery devices, and increasing acceptance by the provider community, such interventions as preoperative bowel preparation, wound care, and infusion therapy ranging from antibiotics to chemotherapy can be administered in the home. This phenomenon is reflected by the increasing flow of literature supporting home infusion therapy for pneumonia, osteomyelitis, skin and soft tissue infections, Lyme

disease, endocarditis, cancer, and acquired immunodeficiency syndrome.¹

In the present climate of cost consciousness, new techniques are evolving for the delivery of healthcare outside the traditional hospital setting. In this study, we explored the safety and efficacy of in-home continuous intravenous anticoagulation therapy with heparin in patients making the transition between intravenous heparin therapy and oral warfarin for a surgical or diagnostic procedure or for the treatment of deep vein thrombophlebitis (DVT). This report describes the results of the initial experience with the program.

... METHODS ...

Patients

Patients selected for outpatient continuous intravenous heparin therapy were prescreened for appropriateness of the home environment (presence of a telephone, potential "hazards"), distance from an acute care facility, willingness to participate, and ability to understand the technical demands of the infusion. Aspirin and nonsteroidal anti-inflammatory drugs were discontinued prior to program initiation. The presence of a second live-in caregiver/support person for technical and emotional support was also required for participation.

Patient Education

Skilled cardiovascular nurses provided clear and concise information about nurse and physician contact, heparin and its complications, care and patency determination of intravenous lines, and home safety instructions. Nurses were guaranteed to be available on an uninterrupted basis (24 hours per day, 7 days per week), to answer patients' questions, replace non-functioning access lines, replenish heparin, adjust drug doses, maintain infusion devices, and perform blood coagulation tests. Nurses communicated coagulation results and patient-status reports to the patients' physicians during each visit.

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Technology

Small programmable infusion devices (CADD-PLUS or equivalent) were used to maximize patient mobility during continuous drug delivery. Prothrombin time (PT) and activated partial thromboplastin time (APTT) were tested by finger stick, using portable coagulation measurement units (Biotrak, HemoChron, Hemotec).

Dosing

All clinical decisions related to the dosing of heparin and warfarin and therapeutic end points were the sole responsibility of the attending physician.

... RESULTS ...

Before starting continuous intravenous home heparin therapy, verbal permission for participation was obtained after the visiting nurse thoroughly explained the program. The acceptance rate was 94% (50 of 53 patients). The first 50 consecutive patients receiving in-home continuous intravenous heparin therapy are reported. The mean age of the participants was 55.7 ± 13.1 years (range, 24 to 76 years). Eighteen patients were older than age 64. Twenty-five patients received heparin prior to a procedure, 3 after a procedure, and 17 both before and after a procedure. The group included 20 women and 30 men whose underlying diagnoses and procedures are listed in Tables 1 and 2, respectively.

During treatment, the mean APTT (normal, 51 to 59 \pm 2.9 seconds) of the cohort was 72.68 ± 37.4 seconds (range, 28 to 280 seconds). Of the 226 measurements, only two values were less than 30 seconds, and four values were less than 40 seconds. Seven measurements were greater than 100 seconds. All the outlier values were corrected to a therapeutic level by the time of the succeeding measurement.

There were no bleeding or thrombotic complications. One patient with supertherapeutic APTT levels had a small, clinically insignificant hematoma at the site of a Portacath insertion and required no adjustment of the heparin infusion rate. Three intravenous lines infiltrated and were replaced without sequelae.

The patients were weaned from oral anticoagulation therapy after a variable duration of intravenous heparin to coincide with the time of the scheduled procedure. The mean PT at the time of weaning from oral anticoagulation therapy was 13.36 ± 1.3 seconds (range, 11.5 to 15.4 seconds). No patient required vitamin K, and only one surgical procedure was postponed because of PT prolongation. For patients requiring initiation or reinstatement of warfarin at the conclusion of a procedure, the mean postprocedure PT was 17.9 ± 2.65 seconds (range, 13 to 21.1 seconds) after intravenous heparin discontinuation.

The average duration of continuous intravenous heparin treatment was 6.1 days (range, 1 to 50 days). For the 45 patients undergoing a procedure other than treatment of acute DVT, the duration encompassed both the pre- and postoperative periods; for the 5 patients with acute DVT, it represented completion of parenteral therapy at home (4 patients) after early hospital discharge (3 to 4 days) or primary treatment without hospitalization (1 patient).

Each day of continuous intravenous heparin therapy represented an avoided day of hospitalization, with an average calculated cost saving per patient of \$4,788. This figure takes into account all costs of intravenous home heparin administration (physicians, nurses, medication, laboratory studies, and supplies).

After patients completed the program, a telephone survey was conducted to assess their satisfaction; a 98% satisfaction rate was reported. The only negative response was from a single patient, who was concerned that the heparin would "run out." This concern led to progressive anxiety and ultimate dissatisfaction. Nevertheless, the patient's entire course of treatment was administered in the home setting.

Table 1. Primary Underlying Diagnosis Requiring Anticoagulation Therapy

Diagnosis	Number
Atrial Fibrillation	5
Prosthetic Aortic and/or Mitral Valve	17
Coronary Artery Disease	7
Carotid Artery Disease	3
Peripheral Vascular Disease	4
Congestive Heart Failure	1
Deep Vein Thrombosis—Acute	5
Deep Vein Thrombosis—Chronic	6
Superior Vena Cava Syndrome	1
Portacath Thrombosis	1

Table 2. Procedures

Procedure	Number
Diagnostic or Therapeutic Catheterization	13
Colonoscopy	7
Cystoscopy	2
Surgery	23
Treatment of Acute Deep Vein Thrombophlebitis	5

... DISCUSSION ...

Physicians faced with the preoperative and/or pre-procedure preparation of a patient given oral warfarin for anticoagulation therapy have four immediate options: (1) discontinue warfarin and wait for the PT to drop to 1.3 to 1.5 times the control and then perform the procedure; (2) discontinue warfarin and substitute outpatient subcutaneous heparin therapy until the procedure is performed; (3) discontinue warfarin, give vitamin K, and then perform the procedure; or (4) discontinue warfarin and maintain continuous heparin administration until the time of the procedure. Among other factors, this decision could be based on the response to the question, "Do all patients for all procedures benefit from heparin therapy?"

Recently, Litin and Gastineau² defined a "low-risk" subset of patients who safely could discontinue warfarin for several days prior to an intervention without heparin coverage, and a subset at increased risk for thromboembolism who would require continuous heparin therapy during warfarin withdrawal. Similarly, White et al³ actually stopped warfarin therapy in a population that Litin and Gastineau would have classified as low risk. With close monitoring over a 5-day period, 22 patients had a gradual decline in the internationalized normalized ratio without thrombosis. This result suggests an alternative to hospitalization or in-home administration of heparin for "low-risk" populations. According to these criteria, 6 of the 50 patients reported in this study would have been characterized as "high risk," requiring treatment in a hospital setting.

Shifting the site of select healthcare interventions to the home has several theoretical advantages: non-acutely ill patients prefer the comforts of home to hospitalization,⁴ the risk of nosocomial infection is decreased, and the overall cost of care is reduced. From a practical standpoint, cost reduction and patient satisfaction must be achieved without sacrifice of safety or efficacy.

For the 50 patients in this study, the continuous administration of intravenous heparin at home achieved these goals. Through the joint efforts and coordination of a "team" (a home nursing service, cooperative physicians, and an educated and willing patient), therapeutic anticoagulation was uniformly accomplished without adverse events and with consistent patient satisfaction and reduced cost. The combined professional and technical expenses for home care were 30% to 40% less than those for comparable in-hospital treatment.

Heparin acts as an inhibitor of thrombin and its generation. It has a narrow therapeutic-to-toxic ratio,

and anticoagulant responses to standard doses are extremely variable.⁵ Continuous administration of heparin requires careful and frequent monitoring of coagulation parameters. To achieve continuous monitoring outside the traditional hospital setting, we mandated the use of in-home coagulation measurements coupled with continuous nurse availability for clinical and laboratory reevaluation of participants. Care was not limited to daylight hours or to any preset schedule or number of nursing visits.

Continuous home heparin infusion therapy was previously described in two individual case reports. Homza⁶ described this intervention in a cancer patient in 1991; in 1994, Ferraris et al⁷ summarized their experience with continuous infusion of intravenous heparin during the last two trimesters of pregnancy in a woman with a mechanical heart valve prosthesis. In both reports, therapeutic anticoagulation was achieved with no adverse effects, and the level of anticoagulation was monitored with the APTT test performed in the traditional hospital laboratory. This strategy is somewhat inefficient, because hours generally elapse between venipuncture and any adjustment of the heparin infusion rate as a result of delivery of the blood sample to the hospital, transfer of the sample to the coagulation laboratory, APTT and PT determination, reporting of results to the nurse and responsible physician, communication between the nurse and physician, and travel back to the home for dose adjustment.

The availability of portable coagulation monitoring devices suitable for home use distinguished the present study design and population from those in previous case reports in the literature. The real-time availability of reliable coagulation measurements increased physician comfort with the concept of administering intravenous heparin in the home setting. Immediate measurement and communication of results to the responsible physician from the on-site nurse ensured prompt adjustment of heparin infusion rates and decreased the likelihood of bleeding or thrombosis. All patients were treated with therapeutic doses of heparin during the transitions to and from oral anticoagulation therapy. Subtherapeutic or excessively prolonged APTT values were corrected promptly, which further minimized the possibility of adverse bleeding or thrombotic events.

The APTT is a whole blood test of the intrinsic coagulation pathway. Past results with a bedside monitor that performs the APTT and PT tests compare favorably with simultaneous APTT and PT results obtained from the traditional laboratory.⁸⁻¹⁰ This portable device has been used regularly for monitor-

ing coagulation during cardiac surgery,¹¹ and in the emergency room and intensive care settings for patients receiving anticoagulation agents after thrombolytic therapy.¹²

Several different portable devices measure the APTT and PT. Each uses a different clot-detecting system, with resultant varied end points generated for "normal" values.¹³ Physicians must be familiar with the specific characteristics of the device used and the values that encompass therapeutic, subtherapeutic, and toxic states. For consistency of clinical decision making, the home infusion service should use only one device, communicate its unique characteristics during each physician phone call, and perform control tests with a "standard" blood sample on a regular basis.

The safety of the program also is dependent on patient selection. In this study, patient screening by both the nurses and physicians eliminated three inappropriate candidates for in-home infusion of heparin. However, this perceived benefit skewed the patient satisfaction results, as the patients objecting to the process were not included in the program.

The average age of 55.7 years, with 18 members older than age 64, was different from the population described in previous case reports. With vigilant screening accompanied by family support and patient education, even elderly patients can receive continuous in-home infusion of intravenous heparin.

Our experience with patients with DVT also was favorable. This diagnosis was not on the initial inclusion list for participation. However, physicians' satisfaction with early program experiences encouraged them to initiate continuous heparin treatment for the five patients with DVT. Four of the patients had shorter-than-average hospital stays, and one was not hospitalized for acute DVT. All were treated at home without adverse effects, rehospitalization, or recurrence of DVT. At-home treatment represented an alternative to classical inpatient anticoagulation therapy¹⁴ and treatment with low-molecular-weight heparins and unfractionated heparin.¹⁵

Our experience with a select group of 50 patients does not provide incontrovertible evidence of the safety and efficacy of this program. However, our pilot study demonstrated safety and the ability to achieve therapeutic anticoagulation in an out-of-hospital setting with a reduction in overall cost.

Clinical Implications

The evolution of home infusion services from a "hospice mentality" to primary management of patients outside the hospital is becoming routine in the present healthcare environment. The impact of this

process on the training of future healthcare deliverers, the current practicing physician population, and hospitals requires a shift, not only in site of service, but in paradigm: as the limits of alternative medical therapy expand, current patterns of treatment based on tradition and intuition will be replaced, and more patients with large burdens of illness will receive medically appropriate and cost-effective care at home.

We have shown that continuous intravenous heparin can be delivered safely to outpatients with a variety of underlying illnesses. Because of a high level of comfort with the process, we have begun a pilot program to expand this program to an early discharge protocol following intracoronary stent placement.

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