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ORIGINAL ARTICLE

Hospital versus home treatment of deep vein thrombosis in a tertiary care hospital in Saudi Arabia: Are we ready?

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KEYWORDS

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Abstract *Aim/Background:* Treatment of DVT with LMWHs has been shown recently to be as effective as UFH with suggested lower costs. This study was conducted to determine and compare the cost of in-patient hospital treatment versus outpatient hospital treatment of patients with DVT.

Method: All adult patients with acute proximal DVT referred to the Emergency Department of King Khalid University Hospital, Riyadh, Saudi Arabia between August 2009 and August 2010 were invited to the study. An economic analysis was performed to compare the cost impact of out-patients versus hospital treatment.

Results: Sixty-one patients were included in the study, 31 were followed in the outpatient setting and 30 as the control group (inpatients). There were no significant differences in the outcome between the outpatient and inpatient group; three patients (9.7%) in the outpatient group and four patients (13.3%) in the inpatient group had recurrent DVT. Mean nursing cost was \$55 for the outpatient group and \$215 for the inpatient group, mean laboratory monitoring cost was \$638 for outpatient group and \$1511 for the inpatient group. Hospital stay and doctor's fees amounted to a mean of \$1000 for outpatient treatment and \$2387 for inpatient treatment, $p < 0.0001$. The mean outpatient cost was significantly lower than the inpatient cost (\$1750 vs. \$4338, $p < 0.0001$).

Conclusion: Outpatient treatment of patients with DVT using LMWHs is cost-effective with no significant differences in the outcome of patients. OPD treatment of DVT is feasible in Saudi Arabia provided there is enough logistic support from thrombosis clinics and those involved in DVT care.

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1. Introduction

Population – based studies have shown that the annual incidence of deep-vein thrombosis (DVT) can be as high as 0.48–1.6 per 1000 persons (Silverstein et al., 1998; Nordstrom et al., 1992).

As a consequence, the management of DVT incurs considerable health care costs. Anticoagulant therapy is the cornerstone

of the management of venous thromboembolism (VTE). In the past, the standard treatment of DVT was intravenous unfractionated heparin (UFH), usually administered for 5–7 days (Hirsh, 1991). However, because the response of patients to UFH varies, laboratory monitoring of the anticoagulant effect is needed, generally requiring admission of the patient to hospital (Hirsh, 1991; Hirsh et al., 1976). In addition when treating DVT with UFH, failure to achieve an adequate therapeutic PTT level within the first 24 h increases the risk of a recurrent VTE (Hull et al., 1997).

In recent years, clinical studies of DVT treatments with low molecular weight heparins (LMWHs) administered once- or twice- daily have shown that LMWHs are at least as effective and as well tolerated as UFH (Simonneau et al., 1993; Hull et al., 1992; Lindmarker and Holmstrom, 1994; Fiessinger and Lopez, 1996; Columbus Investigators and in the treatment of patients with venous thrombosis, 1997; Merli et al., 2001). Furthermore, evidence from meta-analyses suggests that LMWHs may be more effective than UFH for treating DVT (Leizorovicz et al., 1994; Lensing et al., 1995; Siragusa et al., 1996). LMWHs also have advantages over UFH such as subcutaneous rather than intravenous administration and laboratory monitoring of patients is not needed (Hull et al., 1992; Walenga et al., 1991; Prandoni et al., 1992). This allows patients to be treated in an outpatient setting (at day clinics) which can increase patient's convenience and lower treatment costs (Van den Belt et al., 1998; Gould et al., 1999; Belcaro et al., 1999; Lindmarker and Holmstrom, 1996). Despite this, only around 20% of outpatients diagnosed with DVT receive treatment in an outpatient setting (Goldhaber and Tapson, 2004).

In Saudi Arabia, the initial management of uncomplicated DVT is still with UFH in a hospital inpatient set-up because of under-developed logistic support from thrombosis clinics. This study was conducted to determine and compare the cost of inpatient hospital treatment versus outpatient hospital treatment of patients with DVT. Ethical approval was obtained from the Deanship of Scientific Research, College of Medicine, King Saud University, Riyadh, Saudi Arabia (#08–632) dated 14 June 2008.

2. Methods

This is a prospective randomized clinical study, in which patients were randomized to outpatient treatment with LMWH or inpatient treatment with the conventional UFH for a minimum of 5–7 days. All symptomatic adult patients (aged over 18 years) with acute proximal DVT of the lower limbs referred to the Emergency Department of King Khalid University Hospital, King Saud University, Riyadh, Saudi Arabia between August 2009 and August 2010 were invited to the study. Patients were randomly assigned into two groups: (a) inpatient treatment group where they will be treated with the standard UFH protocol or to the (b) outpatient treatment group where they will receive LMWH subcutaneously once daily as outpatients. All patients received Vitamin K antagonist according to warfarin nomogram. Study treatment with UFH or enoxparin was discontinued when the patient had received at least 5–7 days of treatment and INR had been maintained above 2 for 48 h.

Incremental cost analysis incurred by the institution while using the outpatient DVT treatment was performed and was compared to the cost incurred among patients admitted for

treatment. The cost consequences of replacing inpatient care with outpatient care were assessed only during the first 10 days of treatment, since the treatment will not differ appreciably thereafter. Only direct medical costs were taken into account including the number of days of treatment, the number of nursing visits, US scans, number of physician visits and number of blood tests requested. The resources used and costs were direct hospital costs, expressed in US dollars. The cost of treatment of complications, such as hemorrhage were excluded from the evaluation. All calculations were reflected in US dollars.

3. Results

During the one-year evaluation period, a total of 103 patients were seen and invited to join the study, wherein only 61 (59.2%) gave full consent for the study. Of the 61 patients, they were randomized into two groups; 31 into the study group who were followed in the outpatient setting and 30 as the inpatient/control group. Mean age of both groups were 49.2 ± 16.5 years for the outpatient group and 48.4 ± 19.8 years for the inpatient group ($p = 0.854$). All patients in the outpatient group had therapy initiated in the emergency department. Three patients (9.7%) from the outpatient group and 4 patients (13.3%) from the inpatient group had recurrent DVT.

The mean direct cost (in US dollars) for outpatient treatment of DVT was \$1750 (95% CI \$1530 – 1969), which was significantly lower than the mean direct cost for inpatient treatment with UFH (\$4338, $p < 0.0001$) (Table 1). Mean nursing time was 4.2 ± 2.3 days for the outpatient group and 16.4 ± 11.5 days for the inpatient group. This translated to a mean cost of \$55 for the outpatient treatment and \$215 for outpatient treatment, a mean savings of \$160 in nursing costs when patients were treated as outpatients. The mean costs for laboratory monitoring including medical imaging procedures, anticoagulation monitoring and laboratory tests such as complete blood count, INR, PT, APTT, serum creatinine and antifactor Xa levels was significantly lower in the outpatient treatment group compared to the inpatient group (\$638 vs. \$1511, $p < 0.0001$). Hospital stay and doctor's fees amounted to a mean of \$1000 for outpatients versus \$2387 for inpatients, $p < 0.0001$. Treatment of DVT costs significantly more using unfractionated heparin (mean of \$225) compared to an outpatient treatment with LMWH (mean of \$57), $p < 0.0001$.

4. Discussion

This study was conducted to evaluate the effectiveness, safety, and economic impact of an outpatient treatment program versus inpatient treatment for patients with a diagnosis of acute DVT. Our study confirms the results from a growing number of investigations that have demonstrated considerable cost savings with outpatient management of DVT. In our analysis, this study concluded that the two treatment strategies are equivalent; since treatment outcomes were similar. In fact, there were no significant differences in the development of recurrent DVT in either those who had UFH to those who had outpatient treatment with LMWH (9.7% had recurrent DVT in the outpatient group versus 13.3% from the inpatient group). This study found an economic advantage for LMWH over UFH, although some reports suggested that LMWH and UFH are equivalent. The American College of Chest

Table 1 Cost analysis: comparison between inpatient and outpatient therapy of patients with DVT.

	Study group (LMWHs) <i>N</i> = 31	Control group (UFH) <i>N</i> = 30
Nursing costs, in US \$	55.00	215.00
Laboratory costs, in US \$	638.00	1511.00
Hospital costs incl. doctor's fee, in US \$	1000.00	2387.00
Medicine cost, in US \$	57.00	225.00
TOTAL COST	1750.00	4338.00

Physicians Consensus conference program estimated that use of LMWHs for outpatient therapy could save approximately \$250 million US dollars annually in the United States (Leizorovicz et al., 1994). In some other reports, for every patient with DVT treated as outpatient could save as much as \$6000 compared with an inpatient UFH treatment. In this study, outpatient therapy with LMWHs saves approximately \$2588 US dollars per patient, significantly lower than reports from other studies (Van den Belt et al., 1998; Gould et al., 1999; Belcaro et al., 1999; Lindmarker and Holmstrom, 1996).

Although several studies supported the safety and efficacy of LMWH for outpatient management of DVT, mortality advantage is still under question, since deaths are not ascribed to DVT. However, there is recent evidence that comparable results pertaining to safety and efficacy of LMWHs are achievable (Leizorovicz et al., 1994). Some reports have advocated strict exclusion criteria when considering outpatient LMWH therapy for acute DVT especially when it comes to body weight and presence of cancer (Spyropoulos, 1999). However, some reports have shown that even cancer patients who were included in outpatient treatment programs with LMWH achieve similar clinical outcomes with their inpatient counterparts (Tillman et al., 2000). Therefore, a strict exclusion criteria is unnecessary to withhold LMWH therapy in patients who may benefit from it the most.

Treatment of DVT with LMWH in an outpatient setting is feasible, therefore, in Saudi Arabia. In Saudi Arabia, while outpatient treatment of DVT with LMWH follows a standard protocol of care, there are major concerns about the level of supervision, compliance and monitoring of patients undergoing outpatient treatment with LMWH. It may not be sufficient just to rely on the results of several clinical trials that have advocated the use of LMWH in routine practice. Resources and supervision in clinical trials dealing with outpatient treatment of DVT are usually greater than those in routine care.

There is an urgent need to provide logistic support among thrombosis clinics and thrombotic specialists. A multidisciplinary approach involving general practitioners and primary care physicians, residents and consultants involved in the management of DVT to inform and teach patients about the problem, its management and complications is needed. A joint collaborative effort should also be in-line to continuously monitor and further investigate problems encountered in the management of these patients. The successful implementation of an outpatient DVT management should include a carefully designed protocol not only directed toward initial evaluation and diagnosis but more importantly to patients' education and support as well. Once a diagnosis of DVT has been confirmed and the

patient is considered eligible for outpatient treatment, the emergency physician and nurse should provide the basic information necessary for patient's knowledge such as; reasons for anticoagulation, importance of compliance, the importance of monitoring and follow-up and the changes in warfarin dosage and administration. Proper education of the patient on the possible side effects, potential drug interactions and risks of anticoagulation is needed. Prior to leaving the institution, patients should be informed of the schedule of laboratory testing and warfarin dose adjustments. If possible, daily home nursing visits could accomplish this goal along with monitoring patient's compliance and presence of complications and side effects. In a primary care set-up, it would be desirable to involve the family doctor, general practitioner or a primary health care physician who has a better knowledge of the patient's medical history, compliance and social situation. A joint or shared responsibility can be most appropriately implemented such for anticoagulation, cancer screening and monitoring of platelet count after starting outpatient treatment. Patients should be encouraged to report any complication or side effect they notice. In order to accomplish these interrelated management tasks of DVT home treatment, a collaborative system of care should include social services and home nursing care in-line with the hospital-based system of care operating in a seamless coordinated care.

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