Venous thromboembolism registry: a route to improved patient outcomes

Over the last 3 decades, the practice of medicine in the field of venous thromboembolism (VTE) has evolved enormously. An understanding of the pathophysiology of thrombosis and findings from clinical trials indicating the need for thromboprophylaxis (Geerts et al, 2001) have been key developments. However, it is the movement of VTE treatment to the outpatient setting that has most radically altered clinical practice.

The introduction of low molecular weight heparin (LMWH) in the 1990s revolutionized the early treatment of VTE. Clinical studies demonstrated that weight-adjusted, subcutaneous LMWH was at least as effective and safe as laboratory-monitored, intravenous heparin in hospitalized patients with deep vein thrombosis (DVT), with simpler dosing and no need for routine laboratory monitoring (Gould et al, 1999; Dolovich et al, 2000; Merli et al, 2001). In December 1995, Professor Jack Hirsch presented data at the American Society of Haematology that demonstrated, for the first time, the feasibility and safety of LMWH for the treatment of DVT in an out-of-hospital setting. These new data signalled a major shift in the approach to treating VTE, the consequences of which are still not fully manifest today.

This movement to outpatient management was particularly apposite when, in the late 1990s, there was increasing pressure on hospital admissions in the UK, particularly in the winter months, which resulted in a renewed focus on those conditions which could be managed out-of-hospital. A pilot study of outpatient treatment of DVT was initiated at that time at three centres in the UK. Data were collected manually, which proved to be a major logistical challenge. Nonetheless, 1347 patients with DVT were enrolled, with 82% treated as outpatients. Most hospitals now have an outpatient VTE treatment programme, but a national approach to data collection has been lacking. The idea for a national database was formulated in 2001 and VERITY (VEnous thromboembolism RegIsTrY) was launched, funded by an educational grant from Aventis.

THE VERITY PROJECT

VERITY is a UK, prospective, observational registry which aims to characterize the management and define outcomes after outpatient treatment with a LMWH (enoxaparin) to improve the quality of care for patients with VTE. Hospitals are supplied with dedicated software. Information on demographics, risk factors, medical history, symptoms, clinical characteristics, treatment and outcomes are recorded.

A key feature of VERITY is that VTE management and treatment outcomes can be viewed in the context of everyday clinical practice, as opposed to the controlled conditions of a clinical trial. This may lead to a streamlining of the VTE management process and dissemination of best practice. A VERITY website (www.verityonline.co.uk) has been developed to facilitate investigator communication. An annual report is published each year (O'Shaughnessy et al, 2003) and five abstracts have been presented at national and international meetings.

VERITY: CURRENT STATUS

At the end of the first year (2002) 2742 patients with suspected VTE had been submitted by 15 centres. By December 2003, 11 276 patients at 34 centres had been enrolled. Further year on year increases in participation are expected and it is anticipated that by 2005 there will be up to 50 000 patient referrals.

In the first data review, of the 2742 cases, 561 (20%) had a confirmed diagnosis of VTE, 476 DVT and 65 pulmonary emboli (PE), with a further 20 cases of concomitant DVT and PE. Among cases of confirmed VTE, 9% of patients had undergone recent surgery (orthopaedic surgery in 65%), 17% had been medical inpatients or had been recently immobilized for >3 days and 14% were cancer patients. An analysis of the age distribution of cases confirmed that VTE is a disorder of later life. VTE risk increased sharply with age for both sexes with a peak incidence in the 8th decade. A single risk factor was the most common finding, both in the referred population as a whole (586/2742; 21%) and among confirmed cases of VTE (169/561; 30%).

Findings on diagnostic methods showed that D-dimer testing had a negative predictive value >99% but confirmed its limited usefulness in making a positive diagnosis of VTE (specificity ~34%). Most centres combined D-dimer testing with a Wells pre-test probability score. Among patients with confirmed DVT, 86% (402/476) were suitable for home treatment and in cases of confirmed PE, the figure was 38%. This confirms the view that outpatient treatment of PE, although not a widespread practice, is feasible in a substantial proportion of cases.

A preliminary analysis of the 2003 data showed 10 258 entries, with 2167 confirmed cases of DVT and 176 confirmed PE (with or without DVT) cases (22.8% of referrals). Additional risk factor data are available including information on VTE related to intravenous drug abuse and long distance travel. Existing findings on VTE in cancer, pregnancy and related to medical and surgical admissions are extended. Of considerable interest are findings related to outcome in patients given LMWH therapy for which data are available on over 1000 cases. The full 2003 analysis has just been completed and was published in April 2004.

CLINICAL GOVERNANCE AND VERITY

Changes in the management of VTE are taking place at a time when increasing demands are being placed on clinicians to provide evidence-based data to justify clinical practice and establish accepted standards for patient management. Clinical governance is designed to deliver these changes and is part of the ongoing reform of the service (Scally and Donaldson, 1998). The implementation of clinical governance has reinforced the need for hospitals to continuously improve the quality of services and maintain high standards of patient care.

To address these crucial issues, new approaches are needed to identify and disseminate good clinical practice on both local and national levels. Such approaches should involve an organization-wide strategy to improve quality of care, involving collaboration between health professionals and exchange of data relating to the provision of care, as well as simplification of the process of care.

One of the key processes laid out by the NHS for transforming patient care is benchmarking (NHS Executive, 1999). The NHS defines benchmarking as the continuous, systematic search for, and implementation of, best practices which lead to superior performance. Benchmarking is described as a proactive and dynamic quality improvement tool by which services can compare themselves with the best (Lugon, 2003). The purpose of benchmarking is to allow meaningful service comparisons and to promote reflection on how these achievements can be transferred to the local setting and thus generate improvement and deliver excellence.

The VERITY registry was conceived and designed to facilitate benchmarking as it relates to the treatment and management of VTE. By supplying accurate and meaningful clinical information, coupled with committed and transparent sharing of data, VERITY should facilitate the dissemination of best practice and lead to uniform improvements in patient care.

By monitoring trends in VTE-related morbidity and mortality and examining current patterns of treatment on a national basis, feedback can be provided to clinicians that will lead to ongoing improvements in treatment and outcome. Such procedures are essential to the success of clinical governance and will empower health-care professionals to develop and improve the management and treatment of VTE through increasing knowledge and sharing best practice.

CONCLUSION

This movement to managing patients with VTE in the outpatient setting is a major development and presents a challenge to ensure uniformly high standards of patient care are achieved. VERITY was conceived as a means of identifying and disseminating best practice by collecting and analysing data relating to the routine treatment and management of patients with suspected VTE from hospitals across the UK. The project is expanding rapidly. Data are analysed and reported on a yearly basis providing a unique resource describing patient characteristics, treatment and outcome in the setting of everyday clinical practice. VERITY is a valuable tool which facilitates benchmarking and supports the current implementation of clinical governance in the NHS. HM

KEY POINTS

- The routine management of venous thromboembolism (VTE) is evolving and treating patients with VTE as outpatients is a key development.
- VERITY (VEnous thromboembolism RegIsTrY) is a UK prospective, observational registry of patients presenting to hospital with suspected VTE.
- VERITY supports the identification and transfer of best practice by collecting and analysing information on patient management, treatment and outcomes in the outpatient setting.
- VERITY is a valuable tool that facilitates benchmarking and supports clinical governance.

Denise O'Shaughnessy
Consultant Haematologist
Southampton General Hospital
Southampton SO16 6YD
Peter Rose
Consultant Haematologist
Warwick Hospital
Warwickshire
Nick Scriven
Consultant Physician
Calderdale Royal Hospital
Halifax
Daniel Cummins
Clinical Nurse Specialist
Southend Hospital
Westcliff on Sea
Essex
Nick Amlot
Medical Advisor
Aventis
West Malling
Kent

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