Capillary testing in an anticoagulant clinic: comparison of two methods

S M Donohue, J M K Dufty, N A Kafkarkou, R Kirwan, D A Taberner

Complaints from patients about the discomfort associated with capillary testing by lancets, and discrepancy between the results of capillary and venous prothrombin time testing prompted a search for an alternative method of sampling. Automatic capillary testing devices have been successfully used in children¹ and were found to be less painful by patients and easy to use by technologists when piloted in our anticoagulant clinic. We tested one such device, the Tenderlett, in our clinic.

Subjects, methods, and results

Ethics committee approval was obtained from the New River Health Authority. All patients in a routine anticoagulant clinic were asked to participate in the study after they had been given oral and written explanations. Thirty seven patients (50% of total attenders) gave written consent and were asked to have two capillary tests—one with the usual lancet method and one with a Tenderlett device (ITC, Margate, UK)—and a venepuncture. The international normalised ratio of the capillary samples was obtained using a KC4A (Baxter) coagulometer, using Manchester thromboplastin (batch CR41) with an in house international sensitivity index calculation of 1.06 (calculated using the standard manual method with Manchester reagent and recommended number of patients' and normal samples). The mean normal prothrombin time is 16.5 seconds. The venous international normalised ratios were performed on an ACL2000 (Instrumentation Laboratory) using PT fibrinogen plus reagent (Instrumentation Laboratory) with an international sensitivity index of 1.22 and a mean normal prothrombin time of 13 seconds.

When asked which method was least painful, 13 of 37 (35%) responders preferred the fingerprick method (either lancet or Tenderlett) and 14 (38%) preferred venous sampling. Ten rated them as equal. When asked to compare the two fingerprick techniques directly 28 (76%) said that Tenderlett sampling was less painful

than the usual fingerprick method. Patients were then asked which method they preferred, overall, scoring 1 for the most preferred and 3 for the least. The Tenderlett device scored 1 in 72% of responses compared with 17% for venous sampling and 11% for the usual fingerprick method. The least preferred method was the venous method in 50% of respondents and the usual fingerprick method in 47% compared with only 3% with the Tenderlett device.

Statistical analysis was performed using the method of Bland and Altman² to compare a new measurement technique with an established one. No difference was shown between the international normalised ratio results obtained from the Tenderlett sample when compared with the usual capillary method (mean bias 0.0006 and limits of agreement -0.53 to 0.53) (fig 1). The venous method tended to show a negative bias compared with the capillary methods. The mean bias was -0.34 international normalised ratio and the limits of agreement -0.99 to 0.30 when compared with the usual capillary method.

Comment

More patients are likely to receive anticoagulant treatment in future as recent work suggests it will benefit patients with non-rheumatic atrial fibrillation.³ The major side effect is haemorrhage,⁴ and accurate monitoring is essential. Patient acceptability of techniques and reproducibility of results are mandatory to ensure optimal benefit from treatment.

Our results show a definite patient preference for the automatic capillary testing (Tenderlett) device. Furthermore, the international normalised ratios produced by either capillary sample techniques were comparable. The differences between venous and capillary methods are substantially explained by the reference thromboplastins used to calibrate reagents. The Instrumentation Laboratory reagent is calibrated using a rabbit brain international reference reagent; the Manchester Capillary reagent is calibrated using the human brain international reference reagent BCT 441. Discrepancy between international reference preparations has been documented⁵ and is being rectified as they are replaced.

This study indicates that capillary prothrombin time using an automatic collecting device is preferred by patients and generates similar results to those obtained with manual techniques. The standardised incision made by such devices may lead to more accurate results, as it abolishes the interoperator variability, and because the incision is controlled the risk of transmitting infection may also be less. The device's ease of use would enable it to be used by patients themselves. The cost of the automatic device (at least 17p for a Tenderlett) might militate against its widespread use in anticoagulant clinics, though it might be possible to use lower grade scientific staff than currently perform the tests.

We thank ITC UK for providing the Tenderlett devices.
Funding: None.
Conflict of interest: None.

Fig 1—Comparison, using Bland-Altman technique, of Tenderlett capillary international normalised ratio (INR) with INR measured by usual capillary method

Department of
Haematology, North
Middlesex Hospital NHS
Trust, London N18 1QX
S M Donohue, locum
consultant haematologist
N A Kafkarkou, chief
biomedical scientist
R Kirwan, senior biomedical
scientist

Thrombosis Reference
Centre, Withington
Hospital, Manchester
M20 2LR
J M K Dufty, computer
programmer
D A Taberner, clinical director

Correspondence to:
Dr S M Donohue,
Haematology Department,
University Hospital NHS
Trust, Nottingham
NG72UH.

BMJ 1996;313:982

- 1 Harpin VA, Rutter N. Making heel pricks less painful. *Arch Dis Child* 1983;58:226-8.
- 2 Bland JM, Altman DG. Statistical methods for assessing agreement between two methods of clinical measurement. *Lancet* 1986; i: 307-10.
- 3 Ezekowitz MD, Bridgers SL, James KE, Carlner NH, Colling CC, Gornick CC, et al. Warfarin in the prevention of stroke associated with nonrheumatic atrial fibrillation. *N Engl J Med* 1992;327:1406-12.
- 4 van der Meer FJM, Rosendaal FR, Vandenbroucke JP, Briet E. Bleeding complications in oral anticoagulant therapy. *Arch Intern Med* 1993;153:1557-62.
- 5 Poller L, Taberner DA, Thomson JM, Mibashan RS, Shinton NK. Effect of the choice of WHO International Reference Preparation for thromboplastin in International Normalised Ratios. *J Clin Pathol* 1993;46:64-6.

(Accepted 3 June 1996)