Patient self-testing of prothrombin time after hip arthroplasty
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Record Status
This is a critical abstract of an economic evaluation that meets the criteria for inclusion on NHS EED. Each abstract contains a brief summary of the methods, the results and conclusions followed by a detailed critical assessment on the reliability of the study and the conclusions drawn.

Health technology
A portable device (CoaguChek) that enabled patients to self-test their prothrombin time (PT) was under evaluation. The CoaguCheck was a battery powered portable device that used laser photometry to measure PT. The comparator was the standard procedure, which consisted of a conventional venipuncture laboratory test performed by a home-health-care nurse.

Type of intervention
Secondary prevention.

Economic study type
Cost-effectiveness analysis.

Study population
The study population included THA Medicare patients who were mentally and physically capable of self-testing. Patients with dementia, Parkinson's disease, or disability of the upper extremities, were excluded.

Setting
The setting was unclear, although it appears to have been home care. The economic study was performed in the USA.

Dates to which data relate
The dates to which the effectiveness and resource use data related were not reported. The price year was not stated.

Source of effectiveness data
The effectiveness evidence was derived from a single study.

Link between effectiveness and cost data
The costing was carried out on the same sample population as that used in the effectiveness analysis. The cost data for the self-testing procedure were obtained prospectively. The cost data for the standard procedure appear to have been obtained retrospectively.

Study sample
Power calculations, to assure a certain power, were not performed in the planning phase of the study. The study sample comprised Medicare beneficiaries who were scheduled for THA, who lived within an hour of their institution, and who were mentally and physically capable of participation. Among the 78 patients invited to participate, 46 (59%) accepted. The final sample contained only 39 patients, because 7 (15%) of the 46 patients who initially agreed to participate were apprehensive or unable to use the portable device. In total, 10 (23%) patients were withdrawn.
Therefore, 29 patients were finally included in the self-testing (CoaguCheck) group. The authors reported that they retrospectively identified a matched control group of Medicare patients. The control patients were matched to the study patients in terms of their age, gender, weight and diagnosis. The exactly number of patients included in the control group was not specified, although it seems to have contained the same number as the self-testing group.

**Study design**

This was a matched case-control study that was carried out in a single centre. The duration of follow-up was 6 weeks. Ten of the 39 patients who finally participated in the study were lost to follow-up because their anticoagulant therapy needed to be stopped (5), they were discharged out of the service area (4), and they were unable to obtain an unsupervised result after training (1).

**Analysis of effectiveness**

The analysis of effectiveness was conducted on the basis of treatment completers only. The primary health outcomes assessed were patient participation and compliance with the protocol, reliability of patient self-testing, and the quality of care. The reliability of the patients' self-test results was measured by comparing the patients’ CoaguCheck results with those of the laboratory venipuncture tests and those obtained by the home-health nurse with the CoaguCheck. Also, the number of finger sticks needed to obtain valid results was assessed. The quality of care was measured according to the percentage of test results within the target international normalisation ratio (INR) range (INR between 1.5 and 2.5). The study groups were comparable at baseline in terms of their age, gender and overall health status.

**Effectiveness results**

The results from the patients’ CoaguCheck test were significantly and positively correlated with the results obtained by the nurse's CoaguCheck test (Pearson correlation r=0.86, p<0.01). There was no difference in the mean INR values between these two methods, (p=0.45).

The patients' CoaguCheck results were significantly and positively correlated with the venipuncture laboratory value (r=0.82, p<0.01).

The mean laboratory result (INR 1.88 +/-0.060) was slightly higher than the mean patient CoaguCheck test result (INR 1.67 +/-0.46), (p<0.05).

The number of attempts required to obtain a valid result with the portable device did not affect the reliability of the test results. Moreover, after the second week of home testing, there was no difference in the number of fingers sticks that the patients needed to obtain a valid result.

The self-testing group stayed within the target therapeutic range (INR of 1.5 to 2.5) significantly more often than the control group, 59.4% versus 39.1%, (p<0.01).

The self-testing group had significantly fewer tests that fell below an INR value of 1.5 than the control group, 33.3% versus 49.4%, (p<0.01)

**Clinical conclusions**

The effectiveness analysis showed that patients can obtain a reliable PT using the self-testing CoaguCheck device in their homes. Moreover, patient self-testing allowed closer monitoring (twice a week versus once a week), resulting in a higher percentage of patients staying within the target therapeutic range.

**Measure of benefits used in the economic analysis**

No summary measure of benefit was used in the economic evaluation. The study was, in effect, a cost-consequences analysis.
Direct costs
The perspective of the study was not reported. The direct costs considered in the analysis were those associated with home-health nurse visits, laboratory tests, device rental and device cartridges. The cost data were obtained from the Medicare Carriers' Manual and the device manufacturer. The unit cost and the quantities of resource used were reported separately. Discounting was not performed because of the short horizon of the analysis. The price year was not reported.

Statistical analysis of costs
The costs were treated deterministically.

Indirect Costs
No indirect cost were reported.

Currency
US dollars ($).

Sensitivity analysis
No sensitivity analysis was performed.

Estimated benefits used in the economic analysis
See the 'Effectiveness Results' section.

Cost results
The total cost per patient was $376 for the self-testing procedure and either $636 (tests performed once a week) or $1,272 (tests performed twice a week) for the standard procedure. Thus, the average saving of using the self-testing procedure instead of the standard procedure was $260 per patient (if 6 PT tests were performed), or $896 per patient (if 12 PT tests were performed).

Synthesis of costs and benefits
Not applicable since, in effect, a cost-consequences analysis was performed.

Authors' conclusions
The self-testing device is a cost-effective and reliable method of monitoring the anticoagulant status in a select group of elderly patients, who are receiving anticoagulant therapy for a short period after total hip arthroplasty (THA).

CRD COMMENTARY - Selection of comparators
The standard care in the authors' institution was chosen as the comparator. This is an appropriate approach for assessing the active value of the self-testing procedure. You should decide whether this may be applicable in your own setting.

Validity of estimate of measure of effectiveness
This was a case-control study with a matched-control group obtained retrospectively. This design might not have been the most appropriate for the study question, although the authors stated that the same nurse had managed the control and intervention group patients with the same clinical objectives. The study groups were comparable at baseline in terms of their age, gender and overall health status. Therefore, it is likely that the risk of bias was low. However, the
analysis of effectiveness was conducted on the basis of treatment completers only, and the sample size was small. Thus, the internal validity of the effectiveness results might have been weakened. The dates during which the effectiveness data were collected were not specified. The study sample appears to have been representative of the study population.

Validity of estimate of measure of benefit
The authors did not derive a summary measure of health benefit. The analysis was therefore classified as a cost-consequence study.

Validity of estimate of costs
The unit cost and the quantities of resource use were reported separately and the sources of the cost data were reported. Discounting was not performed, which was appropriate given the study time horizon. However, the price year was not reported. In addition, it seems that a cost relevant to the perspective adopted (i.e. the cost of the patient selection process) might have been omitted from the analysis. The study sample comprised patients capable of participating. It would therefore have been appropriate to include not only the cost of the training sessions, but also the costs of patient selection. This omission might have influenced the results obtained, but it is unlikely to have altered the study conclusions. The difference in costs between the standard procedure and the patients' self-test might have been slightly overestimated.

Other issues
The authors did not compare their findings with those of other studies. In addition, the issue of the generalisability of the results was not addressed. The feasibility of performing reflation exercises in other settings is limited by the fact that the estimates used in both the effectiveness and cost sides of the analysis were specific to the study setting.

Implications of the study
The results obtained suggested that the self-testing device is a cost-effective and reliable method of monitoring the anticoagulant status in a select group of elderly patients, who are receiving anticoagulant therapy for a short time after THA. Although the authors pointed out some limitations in using the portable device (some patients did not pass the initial training), no recommendation for further research was provided.

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