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## Evaluation of excessive anticoagulation in a group model health maintenance organization

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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

Using phytonadione and/or fresh frozen plasma (FFP) versus the conservative management option in the management of patients with excessive anticoagulation. The conservative management was defined as temporary discontinuation of warfarin therapy until the international normalized ratio (INR) falls to within therapeutic range.

### Type of intervention

Secondary prevention.

### Economic study type

Cost-effectiveness analysis.

### Study population

Patients with episodes of INRs greater than 6.0.

### Setting

Hospital. The economic study was conducted in the USA.

### Dates to which data relate

The effectiveness and resource use data corresponded to patients managed from December 1994 until August 1995. The price year was not clearly reported.

### Source of effectiveness data

Effectiveness data were derived from a single study.

### Link between effectiveness and cost data

The costing was undertaken prospectively on the same patient sample as that used in the effectiveness analysis.

### Study sample

No power calculations were reported. A total of 301 episodes of excessive anticoagulation, corresponding to 248 patients from a total of 262 candidates, was included in the analysis. The conservative management group included 249 episodes, whereas the intervention group (phytonadione and/or FFP) group consisted of 52 episodes.

### Study design

This was a retrospective cohort study conducted in a single group model HMO. The duration of follow-up was not clearly reported.

### **Analysis of effectiveness**

The analysis was based on treatment completers (those with complete or available data). The primary health outcome used in the analysis were the percentage of managed episodes with no sequelae and incidence of major bleeding after initiation of therapy.

### **Effectiveness results**

The percentage of managed episodes with no sequelae was 85.1% in the conservative group versus 44% in the intervention group. For episodes in the 6.0-10.0 INR range, the rate of major bleeding was 0% in the intervention group, and 0.8% ( $P<0.02$ ) in the conservative group. The corresponding figure for the 10.0-20.0 range was 0% in both groups. A higher percentage of episodes with an unknown cause of excessive anticoagulation was found in the conservative management group than in the intervention group.

### **Clinical conclusions**

The study revealed that conservative management was effective in preventing major bleeding in 99% of episodes and phytonadione therapy was 100% effective.

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

Incidence of major bleeding was the main benefit measure.

### **Direct costs**

The quantities of resource use were reported separately from the costs. The costs measured were those associated with hospitalizations, drug acquisition costs, physician and emergency department visits, laboratory, and telephone calls. The specific cost components of these cost elements were not reported. The cost analysis was based on actual data collected between November 1994 and August 1995, and included only the comparisons for the INRs ranges of 6.0 to 10.0, and 10.0 to 20.0 (>20.0 episodes were excluded). The price year was not clearly reported. The perspective was that of a health maintenance organisation.

### **Indirect Costs**

Not considered.

### **Currency**

US dollars (\$).

### **Sensitivity analysis**

One-way simple and 'best-scenario' sensitivity analyses were conducted by varying the efficacy rate of the comparator, and by excluding the hospitalization costs in the intervention group, respectively.

### **Estimated benefits used in the economic analysis**

For episodes in the 6.0-10.0 INR range, the rate of major bleeding was 0% in the intervention group, and 0.8% ( $P<0.02$ ) in the conservative group. The corresponding figure for the 10.0-20.0 range was 0% in both groups.

### **Cost results**

The cost for the 6.0-10.0 and the 10.0-20.0 INRs were \$111.41 and \$152.65 per episode, respectively for the comparator, and \$802.70 and \$346.64 for the intervention.

### **Synthesis of costs and benefits**

The synthesis of costs and benefits was presented only for the 6.0-10.0 INR range since for the other range the comparator was a weakly dominant strategy. The incremental cost per major bleeding avoided after the initiation of the intervention was \$70,540 (relative to the comparator or conservative-management option). The sensitivity analyses for the scenarios to which the 1.5% and 1.95% incidence rates of major bleeding applied, yielded figures of \$47,240 and \$35,400, respectively. The exclusion of hospitalization costs in the intervention group (due to extension of deep venous thromboembolism, in one case, and administration of intravenous heparin, in another) yielded an incremental cost-effectiveness ratio figure of \$13,500.

### **Authors' conclusions**

Conservative management was shown to be safe and cost-effective when the INR was between 6.0-10.0. Based on the present and previously published study findings the American College of Chest Physicians' recommendation of phytonadione administration to patients with INRs ranging from 6.0 to 10.0 may be unnecessary, and conservative management appears to be a reasonable option.

### **CRD COMMENTARY - Selection of comparators**

The choice of comparator was not explicitly justified by the authors. You, as a user of this database, should consider whether this is a widely used health technology in your own setting.

### **Validity of estimate of measure of benefit**

Lack of randomisation casts doubts on the internal validity of the results.

Validity of estimate of measure of cost:

The quantities of resource use were reported separately from the costs and adequate details of methods of cost estimation were given.

### **Other issues**

Given the lack of randomisation and statistical analysis of the costs, the results may need to be treated with some caution. The conclusions reached by the authors may not be justified, given the uncertainties in the data. The issue of generalisability to other settings or countries was not addressed.

### **Implications of the study**

Further studies are needed to validate the evidence for the cost-effectiveness of the strategies compared in this study. To this end, randomized controlled trials would be desirable.

### **Source of funding**

None stated.

### **Bibliographic details**

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### **Indexing Status**

Subject indexing assigned by NLM

**MeSH**

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