Economic impact of recombinant activated factor VII in the control of bleeds associated with abdominal prostatectomy

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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
The health technology studied in this paper was the injection of recombinant factor VIIa (rFVIIa) for the control of bleeding in abdominal prostatectomy. Two doses were examined in the study, a low dose of 20 microg/kg and a high dose of 40 microg/kg.

Type of intervention
Primary prevention.

Economic study type
Cost-effectiveness analysis.

Study population
The study population comprised patients undergoing an abdominal prostatectomy.

Setting
The setting was secondary care. The economic study was carried out in the Netherlands.

Dates to which data relate
The dates to which the clinical effectiveness evidence and resource use data referred were not reported in the paper.
The price year was 2002 to 2003.

Source of effectiveness data
The effectiveness data were derived from a single study.

Link between effectiveness and cost data
The resource use data were collected from the same patient sample that provided the clinical effectiveness evidence.

Study sample
Thirty-six patients were included in this study. Of these, 8 received low-dose rFVIIa, 16 received high-dose rFVIIa and 12 received a placebo. Details of the sample selection methods and patient characteristics were not given in this paper.
Sample size and power calculations were not reported.

Study design
The study was a single-centre, double-blind randomised trial. The methods of randomisation and blinding were not...
reported in the paper. The authors referred to a published article (Friederich et al. 2003, see 'Other Publications of Related Interest' below for bibliographic details). The patients were followed up for the duration of their hospital stay and, consequently, there was no loss to follow-up.

**Analysis of effectiveness**

The health outcomes used in the analysis were blood loss, the number of packed cell units transfused, the duration of surgery and length of inpatient stay. The analysis accounted for all patients included in the study. No adjustments were made for any differences in the characteristics of the three patient groups.

**Effectiveness results**

The mean blood loss was 2,666 mL for the placebo group, 1,577 mL for the low-dose rFVIIa group and 1,222 mL for the high-dose rFVIIa group, (p=0.003).

The mean number of packed cell units transfused was 1.5 for the placebo group, 0.65 for the low-dose rFVIIa group and 0 for the high-dose rFVIIa group, (p=0.001).

The mean duration of surgery was 180 minutes for the placebo group, 126 minutes for the low-dose rFVIIa group and 125 minutes for the high-dose rFVIIa group, (p=0.014).

The mean length of inpatient stay was 12 days for the placebo group, 13 days for the low-dose rFVIIa group and 10 days for the high-dose rFVIIa group, (p=0.35).

**Clinical conclusions**

The authors concluded that the use of rFVIIa reduces blood loss, the number of units of packed cells transfused and surgery time in patients undergoing abdominal prostatectomy.

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

No measure of health benefit was used in the economic analysis. Therefore, a cost-consequences analysis was, in effect, undertaken.

**Direct costs**

The direct costs of the health service were included in the analysis. These were the costs of packed cells transfused, rFVIIa, surgery costs, post surgery inpatient medication and inpatient stay. The resource use data was based on actual resource use by the patients included in the clinical trial. The unit costs were taken from published unit costs for the Netherlands. A complete breakdown of resource use and unit costs was not provided in the paper. The dates to which the resource use data referred were not reported in the paper. The price year was 2002 to 2003.

**Statistical analysis of costs**

The cost data were treated deterministically.

**Indirect Costs**

No indirect costs were included in this study.

**Currency**

Euros (EUR).
Sensitivity analysis
A number of sensitivity analyses were conducted to assess variability in the data and to assess the scope to generalise the results of this study. A threshold analysis appears to have been undertaken.

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

Cost results
The mean cost per patient was EUR 9,602 in the placebo group, EUR 9,958 in the low-dose rFVIIa group and EUR 9,522 in the high-dose rFVIIa group.

Synthesis of costs and benefits
The sensitivity analysis showed that the total costs were sensitive to the number of packed cells transfused in the placebo group, the unit cost of packed cells and the cost of rFVIIa.

Authors' conclusions
The use of recombinant factor VIIa (rFVIIa) lowers treatment costs and reduces surgery time in patients undergoing an abdominal prostatectomy.

CRD COMMENTARY - Selection of comparators
This study compared the use of low- and high-dose rFVIIa with a placebo for the reduction of peri-operative blood loss. You should consider how these options relate to current practice in your own setting.

Validity of estimate of measure of effectiveness
The effectiveness evidence was taken from a randomised controlled trial, which was an appropriate study design. The trial had a small sample size and the authors acknowledged that this limited their study. The authors did not provide any details of the characteristics of the patients, which means that it is not possible to identify whether the sample was representative of the population of patients undergoing abdominal prostatectomy, or whether the three treatment groups were comparable. The method of sample selection was not reported, thus it was unclear whether the methods used had the potential to introduce bias into the study sample. The analysis of the clinical data accounted for all patients included in the study.

Validity of estimate of measure of benefit
No measure of health benefit was used in the economic analysis. The study was, in effect, a cost-consequences analysis.

Validity of estimate of costs
The perspective of the health care service was adopted in the study. As such, all the costs appear to have been included in the analysis. The authors provided a reasonable breakdown of resource use and unit costs. The cost data were treated deterministically and no statistical analysis of resource use was conducted. This means that the extent of uncertainty around these data is not known. However, sensitivity analyses that assess variability in resource use and unit costs were undertaken. A clear price year was identified, which will allow future relation exercises.

Other issues
The authors do not appear to have presented their results selectively. Their conclusions reflected the scope of the analysis and they cautioned against over-interpretation of their findings. This study aimed to assess the costs associated with abdominal prostatectomy in the Netherlands. However, the authors considered the possible differences in costs
that would be incurred in the USA. The authors acknowledged that their study was limited by the short duration of follow-up and that the costs of outpatient visits, home nurse visits and physiotherapy visits were therefore excluded. They also noted that the lack of long-term safety data on the use of rFVIIa in a surgical setting limits their study, but noted that no long-term adverse effects have been found when rFVIIa is used to treat haemophilia.

**Implications of the study**  
The authors recommended that further studies with larger samples and longer follow-up be conducted on the use of rFVIIa in a range of surgical procedures.

**Source of funding**  
None stated.

**Bibliographic details**  

**Other publications of related interest**  

**Indexing Status**  
Subject indexing assigned by CRD

**MeSH**  
Blood Loss, Surgical /prevention & control; Costs and Cost Analysis; Double-Blind Method; Factor VII; Health Care Costs; Intraoperative Complications; Netherlands; Prostatectomy; Randomized Controlled Trials as Topic; Recombinant Proteins

**AccessionNumber**  
22004008387

**Date bibliographic record published**  
30/06/2006

**Date abstract record published**  
30/06/2006