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
Guglielmi detachable coil (GDC) embolization versus no therapy in the treatment of non-surgical intracranial aneurysms.

Type of intervention
Treatment.

Economic study type
Cost-utility analysis.

Study population
Hypothetical patients, average age 40 years, who have been diagnosed with unruptured cerebral aneurysms but who are deemed inappropriate cases for surgical clipping. A separate analysis was undertaken for those deemed inappropriate due to the size, position or morphology of the aneurysm and those deemed inappropriate due to the presence of co-existing medical conditions.

Setting
Hospital. The economic study was carried out in Virginia, USA.

Dates to which data relate
The effectiveness data were taken from studies, previously published between 1969-1995. Resource data were provided by the model, cost data were derived from two sources from 1996. The price year was not explicitly mentioned and is assumed to be 1996.

Source of effectiveness data
Effectiveness data were derived from a review of previously published sources and expert opinion.

Modelling
A decision tree and annual cycle Markov model were used in estimating the costs and benefits. The decision tree was used to determine the initial post-treatment condition of those undergoing GDC embolization. The Markov model was used to determine the subsequent development of the patients condition over time.

Outcomes assessed in the review
The following parameters, used within the model, were assessed from the literature: the failure rate, mortality rate and morbidity rate associated with GDC embolization; the rate of both complete and partial aneurysmal obliteration.
following GDC embolization; the rate of early recanalization; the annual rate of rupture for untreated aneurysms; the morbidity and mortality related to aneurysmal rupture; and the quality adjustments associated with living with a neurological defect following a rupture, and associated with living with an unruptured, untreated aneurysm.

Study designs and other criteria for inclusion in the review
No specific design criteria were identified by the authors.

Sources searched to identify primary studies
Not reported.

Criteria used to ensure the validity of primary studies
Not reported.

Methods used to judge relevance and validity, and for extracting data
Not reported.

Number of primary studies included
Approximately 17 studies were used as sources of estimates for model parameters.

Methods of combining primary studies
Not reported.

Investigation of differences between primary studies
Not reported.

Results of the review
The values of the parameters used within the model for those who were deemed inappropriate due to the type, location or size of the aneurysm were:

20% failure rate, 1% mortality rate and 4% morbidity rate associated with GDC embolization;

38% rate for both complete and partial aneurysmal obliteration following GDC embolization;

15% rate of early recanalization;

an annual rate of rupture for untreated aneurysms of 1.4%;

20% morbidity rate and 50% mortality rate related to aneurysmal rupture;

a quality adjustment of 0.76 associated with living with a neurological defect following a rupture and a quality adjustment of 1 associated with living with an unruptured, untreated aneurysm.

The values of the parameters used within the model for those who were deemed inappropriate due to co-existing medical conditions were:

10% failure rate, 1% mortality rate and 4% morbidity rate associated with GDC embolization;

62% rate for complete and 22% for partial aneurysmal obliteration following GDC embolization;
8% rate of early recanalization;
an annual rate of rupture for untreated aneurysms of 1.4%;
30% morbidity rate and 50% mortality rate related to aneurysmal rupture;
a quality adjustment of 0.76 associated with living with a neurological defect following a rupture and a quality
adjustment of 1 associated with living with an unruptured, untreated aneurysm.

These data were used as the base case inputs into the two separate models.

**Methods used to derive estimates of effectiveness**
The authors used their best estimates for the annual rates of rupture for completely and partially coiled aneurysms; the
annual rate of late recanalization; the spontaneous progressive thrombosis of partially coiled aneurysms and the quality
adjustment associated with living with a GDC embolized aneurysm.

**Estimates of effectiveness and key assumptions**
It was assumed that completely coiled aneurysms are cured without risk of future haemorrhage giving an annual rate of
rupture of 0% for both patient groups, whilst it was assumed that partially coiled aneurysms have a rupture rate similar
to that for partially clipped aneurysms at 0.5% in both patient groups. The annual rate of late recanalization was
assumed to be 3% for those deemed inappropriate due to type, size or position whilst it was assumed to be 2% for those
with co-existing medical conditions. The rate of spontaneous, progressive thrombosis of partially coiled aneurysms was
assumed to be 8% for both patient groups, and the quality adjustment associated with living with a GDC embolized
aneurysm was assumed to be 1 for both patient groups. The analysis for the co-existing medical condition group
involved the assumption of a 3% co-morbid disease-adjusted death rate.

**Measure of benefits used in the economic analysis**
The measure of benefits used within the analysis was quality adjusted life years gained (incremental QALYs). The
models were used to pool information from a variety of sources and determine the costs and benefits associated with
this emerging technology for a cohort of patients.

**Direct costs**
Costs associated with GDC embolization; follow-up angiography; aneurysmal rupture; acute care following cerebral
infarction and annual rehabilitation costs following cerebral infarction were included within the analysis. The costs were
provided per event, the quantities were determined through the model but were not reported separately. The costs for
the procedures were determined using published charges, whilst the costs for rupture and acute and rehabilitation care
for cerebral infarction were taken from a published report detailing costs at academic medical centres. Costs were
discounted at an annual rate of 5%. The quantity/cost boundary adopted was that of the third party provider. The price
year was not detailed explicitly but is assumed to be 1996.

**Indirect Costs**
Not assessed.

**Currency**
US dollars ($).

**Sensitivity analysis**
In order to test the robustness of the results to variability in the data and to identify where results are sensitive and
Further information is required prior to a precise calculation of the cost-effectiveness of GDC embolization. Sensitivity analysis was undertaken. One-way sensitivity analysis was undertaken on the annual rate of rupture for untreated aneurysms, the failure rate, morbidity and cost associated with GDC embolization, the rate of early recanalization, the rate of spontaneous progressive thrombosis of partially coiled aneurysms, the life expectancy factor associated with co-morbid medical conditions, the quality of life adjustment associated with living with an untreated, unruptured aneurysm and the discount rate applied to costs and benefits. Two-way sensitivity analysis was undertaken for the rate of late recanalization and the annual rupture rate for partially coiled aneurysms in the patient group where size, type or position of the aneurysm precluded surgical clipping.

**Estimated benefits used in the economic analysis**

For the patient group who were deemed inappropriate for surgical clipping due to the size, morphology or position of the aneurysm the use of GDC embolization led to a gain of 0.56 QALYs compared with no therapy, at a discount rate of 5%, over the patient’s lifetime. For the patient group who were deemed inappropriate for surgical clipping due to co-existing medical conditions the use of GDC embolization led to a gain of 0.53 QALYs compared with no therapy, at a discount rate of 5%, over the patient’s lifetime.

**Cost results**

For the patient group who were deemed inappropriate for surgical clipping due to the size, morphology or position of the aneurysm the additional costs associated with use of GDC embolization were $13,000, at a discount rate of 5%. For the patient group who were deemed inappropriate for surgical clipping due to co-existing medical conditions the additional costs associated with use of GDC embolization were $10,100, at a discount rate of 5%.

**Synthesis of costs and benefits**

For the patient group who were deemed inappropriate for surgical clipping due to the size, morphology or position of the aneurysm the cost-effectiveness of GDC embolization was $23,000/QALY. For the patient group who were deemed inappropriate for surgical clipping due to co-existing medical conditions the cost-effectiveness of GDC embolization was $19,000/QALY. The sensitivity analysis revealed that the cost-effectiveness of GDC embolization was most sensitive to variation in the annual rate of rupture of untreated aneurysms, with the cost-effectiveness ratio increasing by over 200% as the rate falls from 1.4% to 1% and continuing to increase as rupture rates fall further. As morbidity associated with GDC embolization increases the cost-effectiveness increases particularly in those whose type, size or position precludes surgery, with a cost-effectiveness ratio of $60,000 per QALY associated with morbidity of 8%. For those who were precluded from surgery due to co-existing medical conditions variation in life expectancy impacts upon the cost-effectiveness ratio with large increases in costs per QALY as life expectancy falls below 15 years. There was little impact upon the cost-effectiveness ratio due to variations in the other parameters. For the two-way sensitivity analysis, at high annual rates of rupture for partially coiled aneurysms (1.2%) variation in the rate of late recanalization had significant effects upon the cost-effectiveness in the patient group who were precluded from surgery due to size, type or position of aneurysm, with the cost-effectiveness increasing to $200,000 per QALY at a recanalization rate of 8%.

**Authors’ conclusions**

The use of GDC embolization to treat unruptured intracranial aneurysms, compared with no therapy, is cost-effective when compared with an acceptable cost per QALY cut-off ratio of $50,000. However, the cost-effectiveness is greatly affected by the annual rate of rupture of untreated aneurysms and either moderately or mildly affected by variation in the parameters concerning the efficacy of the GDC embolization procedure.

**CRD COMMENTARY - Selection of comparators**

The rationale for the choice of comparator is clear. For these patient groups, unruptured intracranial aneurysms would remain untreated due to the deemed inappropriateness of surgical clipping. You, as a user of this database, should consider whether these health technologies apply to your setting.
Validity of estimate of measure of benefit
Few details were provided as to the method used to identify studies within the literature, hence it is difficult to comment upon internal validity. However, when determining the annual rate of rupture for untreated aneurysms the authors used the most recent studies to determine both the base case and the range, and, where possible, results from a recent multi-centre study were used as the source of GDC efficacy parameters. Extensive sensitivity analysis has been undertaken to illustrate the impact of variation within the parameters upon the results of the analysis, particularly upon those parameters which were estimated.

Validity of estimate of costs
The use of charges and costs at academic medical centres within the US may be inappropriate for use within the NHS. The resource quantities were not reported.

Other issues
The issue of generalisability to other settings or countries was not addressed. There was appropriate use of modelling to evaluate the costs and benefits associated with the use of GDC embolization.

Implications of the study
Further research into the use of GDC embolization within these patient groups should concentrate particularly upon getting better estimates for the rupture rate for untreated aneurysms.

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None stated.

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