Cost-effectiveness of percutaneous radiofrequency ablation for malignant hepatic neoplasms

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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 examined in the study was radiofrequency (RF) ablation, a minimally invasive technique for the treatment of malignant liver neoplasms, in particular hepatocellular carcinoma (HCC) and colorectal liver metastases (CLM). Percutaneous RF ablation involves the insertion of one or more electrodes into the tumour nodule under imaging guidance. A high-frequency alternating electrical current is then applied and increased temperatures initiate protein denaturation. This strategy reduces the need for an open procedure and can easily be performed on an outpatient basis.

Type of intervention
Treatment.

Economic study type
Cost-effectiveness analysis.

Study population
The study population comprised patients suffering from HCC or CLM, and who were hospitalised for percutaneous RF ablation of liver neoplasm. It was not clear whether these patients had been excluded from surgery or whether they would otherwise have been suitable only for palliative care.

Setting
The setting was hospital. The economic study was carried out at the Harvard Medical School and Department of Radiology, Beth Israel Deaconess Medical Center, Boston, Massachusetts, USA.

Dates to which data relate
Effectiveness evidence and resource use data were derived from studies published from 1985 to 2000, and institutional records from October 1998 to August 2000. The price year was not reported.

Source of effectiveness data
The effectiveness data were derived from a review of the literature and authors' experience.

Modelling
A decision analytic model was used to evaluate expected costs and survival in the study population in order to calculate the cost-effectiveness of RF ablation and palliative therapy over a range of marginal median survival benefits, from 0 to 60 months. Baseline assumptions in the model were derived from the experience of the authors and published literature.

Outcomes assessed in the review
The effectiveness outcomes derived from the literature were data regarding the natural history of the diseases and effectiveness, such as survival data, probability values associated with the occurrence of complications, and efficacy of the interventions. Numerous studies were also examined in order to make assumptions to support the construction of the decision model.

**Study designs and other criteria for inclusion in the review**
Not reported.

**Sources searched to identify primary studies**
The PaperChase (Boston, Ma) was used to search primary studies as sources of the effectiveness evidence. The following index terms were used: 'hepatocellular carcinoma AND radiofrequency ablation'; 'colon AND carcinoma AND metastases AND radiofrequency ablation'. The journal Radiology was also searched using the term 'radiofrequency ablation'.

**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**
The authors reported two primary studies as sources of the effectiveness evidence. However, other studies were also used to support the modelling.

**Methods of combining primary studies**
Not reported.

**Investigation of differences between primary studies**
Not reported.

**Results of the review**
The results of the review were as follows:

The rates of complications per patient were 0.17% for liver failure; 0.057% for hemothorax, for hepatic abscess, for pulmonary embolism, biloma formation, acute cholecystitis, septic shock, and haemorrhage requiring surgery; 0.17% for intestinal perforation; 0.283% for skin burn at grounding pad site; and 0.227% for subcutaneous/peritoneal seeding.

The median survival of patients treated with palliative care was 10 months.

With respect to survival related to RF ablation patients, several survival rates were obtained from the literature, but differed considerably as they were derived from studies based on heterogeneous populations. Therefore, rather than selecting an arbitrary value for the marginal median survival of RF ablation over palliative care, a range of marginal median survival between 1 and 60 months was used. In particular, survival at 6, 12, 24, 36, and 60 months was considered.

Other model input data were not reported in the study.
Methods used to derive estimates of effectiveness
The authors’ experience with a series of 46 patients treated with percutaneous RF ablation from October 1998 to August 2000 was used as the source of effectiveness data regarding the average number of treatment sessions per patient, the use of general anaesthesia, the need for extended overnight observation as an outpatient, the need for inpatient admission, and the number of treatment sessions that needed post-procedural medications.

Estimates of effectiveness and key assumptions
The average number of treatment sessions per patient was 1.59.

The use of general anaesthesia was 4.1%.

The need for extended overnight observation as an outpatient was 9.6%.

The need for inpatient admission was 0.

The overall rate of treatment sessions that needed post-procedural medications was 10%.

Measure of benefits used in the economic analysis
The benefit measure used in the economic analysis was survival, i.e. life years/months. As shown in the effectiveness analysis, a series of possible incremental life year/month values was used to overcome the lack of consistent data in the literature.

Direct costs
A 5% discount rate was used in the analysis for costs of follow-up evaluations. Resource quantities and unit costs were not reported separately. The resource/cost boundary was that of the third party payer (Medicare). The analysis of costs associated with RF ablation included three major components: initial evaluation (outpatient office visit, abdominal computed tomography (CT), and determination of serum tumour marker), outpatient RF ablation procedure (hospital fees incurred by the RF ablation treatment session and observation room time, professional fees, laboratory fees, medication, and repeat abdominal CT at 1 month after the procedure), and follow-up evaluations (hospital and professional fees associated with outpatient abdominal CT with and without contrast material, outpatient office visit, and determination of serum tumour maker). Costs of RF ablation-related complications were also included. Costs of palliative care included costs of initial evaluations (as in the case of RF ablation), and the costs of disease-related symptom control. The estimation of the resources was derived from the authors’ experience and the estimation of the item costs was based on Medicare reimbursement rates appropriate to the authors' institution, all of which seem to have been listed. The expected total costs were obtained from modelling. The price year was not reported.

Statistical analysis of costs
No statistical analysis of costs was reported.

Indirect Costs
No indirect costs were included.

Currency
US dollars ($).

Sensitivity analysis
A range of potential survival benefits (from 0 to 60 months) was considered to overcome the lack of long-term survival data. A threshold analysis was also performed to determine the required marginal survival benefit associated with RF
ablation necessary to match common benchmarks for cost-effectiveness: generous ($100,000/life year (LY) gained), moderate ($50,000/LY gained), and strict ($20,000/LY gained). Several other sensitivity analyses were conducted to test the robustness of the model to variations in the following input parameters: number of lifetime treatments, number of hours of observations per treatment, frequency of follow-up evaluations, cost of each abdominal CT procedure, probabilities of general anaesthesia and post-procedural medication, discount rate, and method of imaging guidance. The type of analysis was a threshold analysis (as stated earlier). Two alternate scenarios of reimbursement were also considered: one based on the recently implemented Outpatient Prospective Payment System (OPPS) and a second scenario based on the assumption that each RF ablation procedure required inpatient admission.

Estimated benefits used in the economic analysis
The incremental median survival benefits were 6 months, 1 year, 2 years, 3 years, and 5 years, derived as part of the sensitivity analysis.

Cost results
The total marginal direct cost associated with RF ablation strategy over palliative care in the base case ranged between $9,158 and $17,461 when the marginal median survival varied between 1 and 60 months.

Synthesis of costs and benefits
Costs and benefits were combined by performing an incremental cost-effectiveness analysis. The incremental (marginal), costs per LY gained, of RF ablation over palliative care were as follows:

when marginal median survival of RF ablation over palliative care was 6 months, $20,424;
when marginal median survival of RF ablation over palliative care was 1 year, $11,407;
when marginal median survival of RF ablation over palliative care was 2 years, $6,731;
when marginal median survival of RF ablation over palliative care was 3 years, $5,034; and
when marginal median survival of RF ablation over palliative care was 5 years, $3,492.

The threshold analysis indicated that to achieve strict ($20,000/LY gained), moderate ($50,000/LY gained), and generous ($100,000/LY gained) cost-effectiveness thresholds, RF ablation would be required to generate 6.14 months, 2.26 months, and 1.10 months of marginal median survival benefit, respectively, compared to palliative care.

The other sensitivity analyses showed that the minimum median survival was 0.79 for a mean number of lifetime treatments of 1.0, to give $100,000/LY gained. The maximum gain in survival was 16.14 for a mean number of lifetime treatments of 5.0, to give $20,000/LY gained. In the different reimbursement scenarios, the costs per treatment session were $3,482.79 and 7,181.67, respectively, in the OPPS and inpatient schemes, meaning that cost-effectiveness could be as low as $3,492 (5-year survival benefit) or as high as $29,518 (6-month survival benefit).

Authors' conclusions
Percutaneous RF ablation was shown to be a cost-effective strategy for the management of patients suffering from HCC and CLM in comparison to palliative care. The procedure can easily reach the survival benefit necessary to meet even a strict cost-effectiveness threshold. A reimbursement setting enhancing the outpatient management of the disease was proved to be important in order to realise substantial cost-saving in comparison to systems favouring the hospitalisation of the patients.

CRD COMMENTARY - Selection of comparators
The rationale for the selection of the comparator was not clear, although palliative care probably represented the routine care for the patients considered in the study. However, the authors did not justify the exclusion of other feasible
interventions not used as comparators. You should consider whether the technique represent a commonly used intervention in your own setting.

Validity of estimate of measure of effectiveness
The effectiveness measures were mainly derived from published studies, but the conduct and methodology of the literature review could have been described in more detail. As the authors acknowledged, data obtained from the literature were not consistent and it was not clear how the single estimates were obtained. In addition, the process of combination of primary studies was not reported. These difficulties were partially overcome by selecting five values of incremental benefit corresponding to five estimations of the impact of the intervention on patients' survival, and by conducting threshold analyses. Finally, the study population was not clearly defined, in particular with regards to suitability for surgery.

Validity of estimate of measure of benefit
The measure of benefit was life years/months, which were either assumed, as noted above, or derived in the threshold analysis.

Validity of estimate of costs
Numerous categories of costs relevant to the perspective adopted were included in the analysis, but the estimation of costs was quite specific to the Medicare reimbursement system. The authors recognised that these cost estimations were based on charges rather than 'true unit costs', but this was due to the perspective adopted. Furthermore, resource quantities were not reported separately and the price year was not stated. However, extensive sensitivity analyses were carried out on the cost items considered.

Other issues
The authors did not make comparisons of their findings with those from other studies. The issue of generalisability to other settings was implicitly addressed by performing several sensitivity analyses on both cost and effectiveness data, and constructing two hypothetical scenarios to assess the impact of reimbursement systems on the results of the analysis. The authors do not appear to have presented their results selectively.

Implications of the study
The authors recommend the adoption of RF ablation as a cost-effective procedure for patients with HCC and CLM. However, they also recommend surgical treatment when possible, and that further research should focus on long-term comparison of RF ablation and surgery on the basis of homogeneous populations. The authors' conclusions of cost-effectiveness need to be tempered by the lack of population definition and the large degree of heterogeneity in benefit depending on the population. However, the analysis demonstrated a means of dealing with such heterogeneity.

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