Outcome and cost comparison of percutaneous transluminal renal angioplasty, renal arterial stent placement, and renal arterial bypass grafting

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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 use of percutaneous transluminal renal angioplasty (PTRA), percutaneous transluminal stent placement (PTSP) of renal arteries, and renal arterial bypass grafting (RABG) in the treatment of renovascular hypertension.

Type of intervention
Treatment.

Economic study type
Cost-effectiveness analysis.

Study population
The study population comprised patients who underwent PTRA, PTSP, or RABG.

Setting
The setting was a hospital (tertiary care). The economic analysis was carried out in Lebanon, New Hampshire, USA.

Dates to which data relate
The effectiveness data were collected between June 1992 and February 1998 from the medical records of the hospital. The dates to which the resource quantities, costs and prices related were not reported.

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

Link between effectiveness and cost data
It was not stated whether the costing was undertaken on the same patient sample as that used in the effectiveness study, nor whether it was undertaken prospectively or retrospectively.

Study sample
No power calculations were performed to determine the sample size. In total, 130 patients were considered in the study.

The indications for PTRA were severe hypertension refractory to medications, with or without renal insufficiency, and angiographic evidence of renal arterial stenosis (RAS), that is, a reduction in the luminal diameter of the renal artery of greater than 50%.

The indications for PTSP were failure to satisfactorily eliminate the stenosis after repeat balloon dilation, intimal
dissection with luminal compromise, recurrent stenosis after previous PTRA, and stenosis involving the renal arterial
ostium.

The indications for RABG were diffuse stenosis or stenosis involving branches of the renal artery that were not
treatable with PTRA or PTSP. Also, patients who had a recurrent RAS after PTRA or PTSP, severe atherosclerosis
involving other abdominal aortic branches in addition to RAS, or a concurrent abdominal aortic aneurysm that needed
surgical repair.

PTRA was performed in 54% of the patients (90 renal arteries in 70 patients), PTSP in 30% (45 renal arteries in 39
patients), and RABG in 16% (26 renal arteries in 21 patients).

The authors did not report evidence that the initial study sample was appropriate for the clinical study question,
although this appears to have been the case.

Study design
This was a retrospective cohort study that used the medical records and angiograms of patients from a single institution.
The allocation of patients to the groups depended on specific indications stated for each alternative treatment. The
duration of follow-up was 12 months.

Analysis of effectiveness
The analysis of the clinical study was conducted on the basis of treatment completers only. The primary health
outcomes assessed in the analysis were success rates, complication rates, improvement of angiographic stenosis, cure of
hypertension, improvement of hypertension, blood pressure, antihypertensive medication, and serum creatinine levels.
The groups were shown to be comparable at analysis in terms of the age, percentage of patients with azotemia, number
of coexistent morbidity factors, baseline systolic or diastolic blood pressure, number of antihypertensive medications,
or serum creatinine levels. However, the male-to-female ratio was significantly different among the treatment groups:
the percentage of women was higher in the RABG group relative to the PTSP group, (p=0.009). Moreover, differences
in the type, (p=0.044), and location, (p=0.042), of the lesions among the treatment groups were reported.

An improvement in hypertension was defined as either a diastolic pressure of less than 90 mmHg with administration of
antihypertensive medication, or a diastolic pressure of 90 to 109 mmHg, with a decrease of at least 15 mmHg with the
same or fewer medications at the same or a lower dose. Stenosis severity was expressed quantitatively as a percentage
of the main renal artery.

Effectiveness results
The overall success rate was 91% for PTRA, 98% for PTSP, and 92% for RABG. There was no statistically significant
difference in the success rate among the groups, (p=0.345).

The overall complication rates were 13% for PTRA, 16% for PTSP, and 38% for RABG. The rate of complications
with RABG was significantly higher than with PTRA, (p=0.004) or with PTSP (p=0.029). The authors also reported
that complications with RABG tended to be more serious than complications with PTRA or PTSP.

Angiographic stenosis improved on average from 72 to 11% with PTRA, from 78 to 2% with PTSP, and from 81% to
patency with RABG. PTSP yielded significantly superior angiographic results in comparison with PTRA, (p=0.007).

Hypertension was cured with PTRA in 6 (9%) patients, with PTSP in 4 (10%) patients, and with RABG in 4 (19%)
patients. Improved hypertension was noted in 53 (76%) patients who underwent PTRA, 28 (72%) who underwent
PTSP, and 16 (76%) who underwent RABG. The differences in the rates of cure and improvement among the groups
were not statistically significant, (p=0.359).

There were no statistically significant differences in the immediate (p=0.122), 6-months (p=0.294), or 12-month (p=
0.091) mean arterial pressure among the groups.
The number of antihypertensive medications taken by the patients immediately after all three treatments was reduced significantly in comparison with the baseline number. On average, the number of antihypertensives was reduced by 0.63 following PTRA, 0.72 following PTSP, and by 0.58 following RABG. No statistically significant difference was found among the groups, (p=0.147). The mean number of antihypertensive medications returned to the baseline after 6 months for RABG, and after 12 months for PTRA and PTSP (p>0.05).

The mean serum creatinine levels did not change significantly and were stable for the 12 months following all three treatments, (p>0.05).

Clinical conclusions
The three alternatives compared did not show significant differences in terms of success rates, improvement of angiographic stenosis, rates of improvement and cure of hypertension, mean arterial blood pressure, and mean serum creatinine levels. However, the complication rates were higher and more serious for RABG. Therefore, PTRA and PTSP were shown to be safer treatments for hypertension caused by RAS.

Measure of benefits used in the economic analysis
No summary measure of health benefit was used in the economic analysis. Therefore, a cost-consequences analysis was carried out.

Direct costs
The direct costs included in the analysis were the average costs of the procedures related to the tertiary care centre.

The total cost for each procedure was broken into procedural costs and post-procedural hospitalisation costs. The procedural costs for PTRA and PTSP were calculated using the calculated hourly rate ($519) multiplied by the duration of the procedure (2.0 +/- 0.4 for PTRA; 2.3 +/- 0.6 for PTSP), plus the cost of consumable supplies ($364). The hourly rate was derived from the costs for labour (physicians, technicians, nurses, receptionists, and secretaries), equipment, supplies, cost for administrative support, facility maintenance, and other overheads, and the post-procedural costs from monitoring and observation of patients who were not hospitalised after PTRA or PTSP. The durations of PTRA and PTSP were determined by averaging the time to perform these procedures in 10 uncomplicated unilateral cases. The average cost of the immediate post-procedural hospitalisation after PTRA and PTSP (required for some of the patients) was also reported. This was $540 for PTRA and $1,779 for PTSP. The procedural cost for RABG was calculated as an hourly vascular surgery rate ($602) multiplied by the duration of the surgery, plus the costs of material ($1,700) and anaesthesia ($2,506).

The post-procedural costs for RABG were determined on the basis of the average duration of hospital stay, considering separately the intensive care unit and the regular hospital costs. The average duration of RABG was determined from four cases of uncomplicated unilateral RAGB without other surgical interventions.

Only uncomplicated unilateral procedures were considered in calculating the total cost per procedure. The justification given for this was that many patients in the RAGB group also underwent other concurrent surgical procedures. When uncomplicated unilateral procedures occurred, no hospitalisation was needed for PTRA or PTSP, whereas an average of 7.0 days of hospitalisation was required for RABG.

The resource quantities and the costs were not reported separately. Discounting was not performed, but would have been irrelevant given the time period considered in the study (12 months). The dates to which the resource quantities and costs related were not reported. The price year was not given. The sources of the costing were two manuscripts in preparation, which were based on data from the hospital.

Statistical analysis of costs
No statistical analysis of the costs was performed. Only the means and standard deviations of the duration of the alternative procedures were reported.
Indirect Costs
No indirect costs were included in the analysis.

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 average total treatment costs for uncomplicated unilateral procedures were $1,402 for PTRA, $2,573 for PTSP and $15,393 for RAGB.

Synthesis of costs and benefits
Not applicable due to the cost-consequences approach adopted.

Authors’ conclusions
Percutaneous transluminal renal angioplasty (PTRA), percutaneous transluminal stent placement (PTSP) of renal arteries, and renal arterial bypass grafting (RABG) had similar success rates. They were also equally efficacious for the treatment of renovascular hypertension in the study population considered in the analysis. However, PTRA and PTSP cost substantially less than RABG, while the clinical outcomes at 12 months for RABG were no better than those for PTRA and PTSP. The initial treatment costs for PTRA and PTSP were substantially lower than those for uncomplicated RABG. A large proportion of the cost for RABG was related to expected complications and unavoidable postoperative hospitalisation.

CRD COMMENTARY - Selection of comparators
The comparators, PTRA and PTSP, were justified on the grounds that they represent actual practice, but there is uncertainty about the outcomes and costs associated with them in comparison with RABG.

Validity of estimate of measure of effectiveness
The analysis used a single cohort study, which was appropriate for the study question. The study sample appears to have been representative of the study population. The authors reported some limitations related to the relatively small sample size and bias in assigning patients to the treatment groups. The patient groups were shown to be comparable at analysis in terms of the age, percentage of patients with azotemia, number of coexistent morbidity factors among the treatment groups, and so on. However, there were some medical indications for each of the procedures that may have affected the comparability of the outcomes among alternative treatments. As the authors reported, another confounding factor in the study was that some patients in the PTSP group had undergone prior PTRA, while some in the RAGB group had undergone either prior PTRA or PTSP. Consequently, these patients in the PTSP and RABG groups might have had more advanced disease. Further, some patients who underwent RABG had additional interventions that may have resulted in the higher complication rates for this procedure. All these biases and confounding factors may have negatively influenced the outcomes of RABG and PTSP. Another potentially confounding variable reported by the authors was the different male-to-female ratio among the treatment groups, the influence of which was not predicted. These features of the study design, in conjunction with potential bias and confounding variables, indicate that a degree of caution should be exercised when considering the reliability of the effectiveness results.
Validity of estimate of measure of benefit
The authors did not derive a summary measure of health benefit. The analysis was therefore categorised as a cost-consequences study.

Validity of estimate of costs
All the categories of costs relevant to the perspective adopted seem to have been included in the analysis. However, the costs and the quantities were not reported separately, and the dates related to the costs and prices were not reported. Further, only uncomplicated unilateral procedures were considered in calculating the total cost. These limitations weaken the generalisability of the results and hinder reflation exercises to other settings. An additional limitation reported by the authors was that the costing was limited only to the initial treatment costs; empirical evidence has shown a higher restenosis rate for PTRA and PTSP, compared with RAGB, which would imply an increase in the long-term cost of follow-up for PTRA and PTSP. However, the authors argued that these results were not accorded to such empirical evidence, and that the total cost of repeat PTRA would still be substantially less than for the primary RABG.

Other issues
The authors made appropriate comparisons of their findings with other studies but did not address the issue of generalisability to other settings. An informative discussion of the limitations and caveats associated with the study was presented. This may be useful in the design of future cost-effectiveness studies in this area of medicine.

Implications of the study
PTRA, PTSP, and RAGB were shown to present similar effectiveness for the treatment of hypertension caused by RAS, although PTRA and PTSP were safer and cheaper than RAGB in the short-term (12 months). However, the study had some serious limitations that necessitate caution when interpreting these results. The authors suggest further research around the total long-term costs of PTRA, PTSP, and RAGB.

Source of funding
Supported in part by the Hitchcock Foundation.

Bibliographic details

PubMedID
10429693

DOI
10.1148/radiology.212.2.r99au20378

Other publications of related interest


Weibull H, Bergquist D, Bergentz SE, Jonsson K, Hulten L, Manhem P. Percutaneous transluminal renal artery


**Indexing Status**
Subject indexing assigned by NLM

**MeSH**
Aged; Angioplasty, Balloon /economics; Arteriovenous Shunt, Surgical /economics; Blood Vessel Prosthesis Implantation /economics; Costs and Cost Analysis; Female; Follow-Up Studies; Humans; Hypertension, Renovascular /economics /therapy; Male; Middle Aged; Renal Artery /surgery; Renal Artery Obstruction /economics /therapy; Retrospective Studies; Stents /economics; Time Factors; Treatment Outcome

**AccessionNumber**
21999001437

**Date bibliographic record published**
31/01/2003

**Date abstract record published**
31/01/2003