Are modified procedures significantly better than conventional procedures in percutaneous transhepatic treatment for complicated right hepatolithiasis with intrahepatic biliary strictures

Jeng K S, Sheen I S, Yang F S

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 modified and conventional procedures in the percutaneous transhepatic treatment of complicated right hepatolithiasis with intrahepatic biliary strictures.

During conventional procedures for percutaneous stricture dilation (PSD) and subsequent transhepatic cholangioscopic lithototomy (PTCSL), one week after the transhepatic route was established, the PTBD tract was dilated from 8.3 to 16 Fr. at 3-day intervals under local anaesthesia. PSD was then undertaken with a balloon catheter via the PTBD tract. PTCSL was then performed by introducing a flexible cholangiofibrescope with a 2-mm working channel into the intrahepatic bile duct through the dilated PTBD tract. The stones were crushed with a Dormia basket catheter via cholangioscopy. Repeated bolus flushing with normal saline was used during lithotripsy and lithotomy. A basket catheter (via cholangioscope) was used to extract retained fragments. Lithotripsy and lithotomy were repeated as necessary.

In the modified PSD and PTCSL procedures, PTBD was established by puncture. Under anaesthesia, dilation of both the percutaneous transhepatic tract and the intrahepatic biliary stricture was accomplished in only one session. The stones were fragmented before extraction with an electro hydraulic lithotriptor probe (EHL) introduced through the cholangiofibrescopic channel. Slow irrigation with normal saline, instead of large boluses of saline, was carried out during cholangioscopy. A basket catheter (via cholangioscope) was used to extract retained stone fragments until all were clear. Thus, the innovation included one-session tract and stricture dilation, EHL and slow irrigation.

Type of intervention
Treatment.

Economic study type
Cost-effectiveness analysis.

Study population
The study population comprised patients diagnosed with recurrent hepatolithiasis in hospital. Recurrent hepatolithiasis was defined as the reoccurrence of intrahepatic stones subsequent to a history of surgical or biliary procedures for hepatolithiasis, after which initial treatment no residual stones had been found on computed tomography scan, endoscopic retrograde cholangiography, percutaneous transhepatic cholangiography, or T-tube cholangiography. The exclusion criteria were:

- retreatment for recurrent stones after percutaneous stone therapy between 1984 and 2000;
- other serious medical illnesses which limited treatment;
- left hepatolithiasis with left hepatic biliary strictures;
coexisting choledocholithiasis;
severe liver cirrhosis (Child’s class C);
prior jejunostomy;
extrahepatic biliary obstruction or stenosis;
coexisting intrahepatic long-segment (greater than 1.5 cm) biliary stricture, a distinct entity requiring stent therapy;
incomplete data or loss to follow-up; and
coexisting cholangiocarcinoma or other malignant neoplasm diagnosed before or during stone therapy.

Setting
The setting was secondary care. The study was carried out in Taipei, Taiwan.

Dates to which data relate
The study comprised patients diagnosed with recurrent hepatolithiasis from January 1984 to December 2000. The price year was not reported.

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

Link between effectiveness and cost data
The costing was undertaken retrospectively on the same patient sample as that used in the effectiveness study.

Study sample
No power calculations to determine the sample size were reported and no specific sample size was planned. A total of 212 patients were diagnosed with recurrent hepatolithiasis in the authors' hospital during the study period. Of these, 40 underwent repeat surgical intervention while 172 underwent PSD and PTCSL. Seventy-two of those treated percutaneously were excluded on account of the exclusion criteria (the numbers for each criteria were given). This left 100 patients with right recurrent hepatolithiasis and complicated intrahepatic biliary strictures. From January 1984 to December 1990, 40 patients (group A) underwent conventional percutaneous treatment. The mean age of the group was 43.9 (+/- 8.3) and 18 (45%) were male. From January 1991 to December 2000, 60 patients (group B) underwent the modified treatment. The mean age of the group was 43.8 (+/- 7.4) years and 28 (46.7%) were male.

Study design
The study was a retrospective comparative study with historical controls, which was carried out at the authors' hospital. The patients were assessed one month after the procedure, and then every 3 to 4 months for the first 3 years and every 6 months thereafter. For the purposes of the study, the analysis of long-term follow-up was terminated in 1992 for group A and in 2000 for group B. Hence the longest possible follow-up for any patient was 10 years after treatment. The mean follow-up period was 70.0 (+/- 50.0) months in group A and 61.0 (+/- 59.0) months in group B. Four patients were excluded from the study because of loss to follow-up or incomplete data. These patients were not included in the analysis and were not part of the 100 patients studied.

Analysis of effectiveness
All the patients included in the study were accounted for in the analysis. The immediate outcomes one month after treatment included:
the number of sessions for each manipulation and post-procedural complications;
the 1-month mortality rate;
the number of patients requiring termination;
the incidence of residual stones;
the number of patients with complete stone clearance; and
the number of hospital days.

PTCSL was judged successful if there was clearance of stones on follow-up cholangioscopy, cholangiography and abdominal sonography.

The long-term outcomes included:
the recurrence of stones and/or cholangitis;
the incidence of cholangiocarcinoma;
late sequelae or secondary biliary cirrhosis with portal hypertension; and
late death.

For this analysis, patients with recurrent stones were excluded. Student's t-test, the Mann-Whitney U-test, the chi-squared test, or Fisher's exact test was used for the statistical analysis. A p-value of less than 0.05 was defined as statistically significant. The groups were shown to be comparable in terms of gender, age and prognostic features.

**Effectiveness results**

The immediate outcomes after treatment were as follows:

6 (15%) patients in group A and none in group B suffered massive haemobilia, (p=0.0032);
7 (17.5%) patients in group A and none in group B suffered from cholangitis, (p=0.0012);
5 (12.5%) patients in group A and none in group B suffered from pain intolerance, (p=0.0087);
8 (20%) patients in group A terminated the treatment prematurely and with residual stones, compared with 2 (3.3%) patients in group B, (p=0.0132);
complete stone clearance was achieved in 32 (80%) patients in group A and 58 (96.7%) patients in group B, (p=0.0132); and
hospitalisation was 36.2 (+/- 5.5) days for patients in group A, compared with 17.8 (+/- 4.4) days in group B, (p<0.001).

There were no statistically significant differences in 1-month mortality and septicaemia between the two groups.

In terms of long-term outcomes, group B had significantly more patients without stone recurrence and who were symptom-free (81% versus 50%; p=0.0021).

**Clinical conclusions**

The study showed that the modified methods resulted in significantly less procedural morbidity, lower treatment termination rates and fewer residual stones.
Measure of benefits used in the economic analysis
No summary measure of benefit was derived. The study was, in effect, a cost-consequences analysis.

Direct costs
Resource use and the costs were reported separately. The direct costs included in the analysis were those of the hospital. These included the establishment of PTBD, tract and balloon dilation, anaesthesia, lithotripsy, cholangioscopic lithotomy and hospitalisation. The sources of the unit costs were not reported. Discounting was not relevant, as the costs were incurred during the hospitalisation hospitalisation, and was not undertaken. The study reported the average costs. The price year was not reported.

Statistical analysis of costs
The costs were treated as point estimates (i.e. the data were deterministic).

Indirect Costs
The indirect costs were not included in the analysis.

Currency
US dollars ($). The exchange rate used for the currency conversion was not reported.

Sensitivity analysis
No sensitivity analysis was performed.

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

Cost results
The mean cost of treatment was $3,848 for group A compared with $2,689 for group B.

Synthesis of costs and benefits
The costs and benefits were not combined.

Authors' conclusions
The modified methods were superior to conventional treatment, as they were effective at decreasing potential complications and cost and they significantly improved treatment results.

CRD COMMENTARY - Selection of comparators
Conventional methods in percutaneous transhepatic treatment were chosen as the comparator because they represented current practice in the authors' setting up to December 1990. You should decide if this is a widely used health technology in your own setting.

Validity of estimate of measure of effectiveness
The analysis used a retrospective comparative study with historical controls, which was based on a retrospective analysis of hospital records. This was appropriate for the study question in that it ensured that a great number of patients were identified. However, this type of study also has many potential limitations. For example, as this study examined
outcomes over two time periods, factors changing over time (e.g. improved medical technologies, better health care delivery, new management styles) might have explained some of the differences between the groups in terms of health outcomes and hospital length of stay. Apart from this limitation, the analysis appears to have been handled credibly. The study sample was representative of the study population, and the patient groups were shown to be comparable at analysis. Exclusion criteria, and the numbers and reasons for patient exclusion were satisfactorily reported. In addition, the authors conducted appropriate statistical tests to test for statistically significant differences between the two groups.

**Validity of estimate of measure of benefit**
The authors did not derive a summary measure of health benefit. The analysis was, in effect, a cost-consequences analysis.

**Validity of estimate of costs**
All the categories of cost relevant to the hospital perspective, which appears to have been adopted in the economic analysis, were included in the analysis, as were all the relevant costs. The costs were reported separately from the quantities, which will enhance the generalisability of the authors' results to other settings. Resource use was derived from the study, with differences in resource use between the groups being appropriately tested for significance. However, the sources from which the unit costs were derived were not reported. Hence, it is not possible to verify the reliability of these estimates. The authors also failed to report the exchange rate used to convert the costs into US$ dollars and the dates to which the prices related. Both of these factors hamper any possible currency conversion or inflation exercises. It was unclear whether charges were used to proxy prices.

**Other issues**
The authors made appropriate comparisons of their findings with other studies, with the authors finding that their modified procedures achieved the best results. The issue of generalisability to other settings was not addressed. The authors do not appear to have presented their results selectively and their conclusions reflected the scope of the analysis. The authors did not report any further limitations to their study.

**Implications of the study**
Based on their study, the authors recommended modified PSD and PTCSL procedures as alternative treatments for recurrent hepatolithiasis with difficult intrahepatic biliary strictures. The procedural modifications included shortening the dilation procedures, using general anaesthesia during dilation, substituting EHL for basket lithotripsy, and using slow saline irrigation rather than bolus flushing.

**Source of funding**
None stated.

**Bibliographic details**

**PubMedID**
12059063

**Other publications of related interest**

Jan YY, Chen MF. Percutaneous trans-hepatic cholangioscopic lithotomy for hepatolithiasis: long-term results.


**Indexing Status**
Subject indexing assigned by NLM

**MeSH**
Adult; Bile Duct Diseases /radiography /surgery; Bile Ducts, Intrahepatic /radiography /surgery; Catheterization /methods; Cholelithiasis /radiography /surgery; Constriction, Pathologic /radiography /surgery; Endoscopy, Digestive System /methods; Female; Humans; Lithotripsy /methods; Male; Middle Aged; Postoperative Complications; Recurrence; Treatment Outcome

**AccessionNumber**
22002000937

**Date bibliographic record published**
30/04/2005

**Date abstract record published**
30/04/2005