Transcranial ultrasound diagnosis of intracranial lesions in children with headaches

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 transcranial ultrasound for the diagnosis of intracranial lesions such as tumours, haematomas or hydrocephalus, in children with headaches. The ultrasound was performed using a 2-MHz-sector sonographic transducer.

Type of intervention
Diagnosis.

Economic study type
Cost-effectiveness analysis.

Study population
The study population comprised children with headaches of more than 2 weeks' duration.

Setting
The setting was a hospital. The economic study was conducted at the Division of Pediatric Neurology at the Chang Gung Children's Hospital, and at the Division of Pediatric Neurosurgery at the National Taiwan University Hospital in Taipei, Taiwan.

Dates to which data relate
The effectiveness and resource use data were gathered from January 1995 to December 1998. No price year was reported.

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

Link between effectiveness and cost data
The costing was conducted prospectively on the same sample of patients as that used in the effectiveness analysis.

Study sample
Power calculations to determine the sample size were not performed. All eligible children who were visited at the study hospitals during 1995 to 1998 were included in the study. Of the initial sample of 444 eligible children, 19 were lost to follow-up and diagnostic assessment failed in two children. Thus, the final sample comprised 423 patients (190 boys and 233 girls) who underwent initial neurologic examination and then both transcranial ultrasound and MRI, if required. The mean age at the onset of headache was 10.4 years (range: 3 - 15). This sample was split into two groups. Thirteen patients with abnormal neurologic signs were grouped into the complicated headache group, while the
remaining 410 patients were included in the isolated headache group.

**Study design**
This was a prospective, case-control study that compared neurologic examination and transcranial ultrasound. All patients in the sample underwent both diagnostic assessments. The study was conducted at the Division of Pediatric Neurology at the Chang Gung Children's Hospital, and at the Division of Pediatric Neurosurgery at the National Taiwan University Hospital in Taipei. The patients were followed for one year and monthly assessments were performed on each patient. Nineteen patients were lost to follow-up. Children with positive transcranial ultrasound findings and those with accompanying, progressing, or newly developed neurologic symptoms or signs underwent further diagnostic tests using MRI.

**Analysis of effectiveness**
Only treatment-completers were included in the clinical analysis. The primary health outcomes were the diagnostic results obtained with neurologic examination and transcranial ultrasound in comparison with MRI, which provided a true assessment. The sensitivity and specificity of the diagnostic tools were then estimated.

**Effectiveness results**
In the complicated headache group, transcranial ultrasound revealed 13 positive results. There were 6 children with brain tumours, 2 with hydrocephalus, 2 with herpes simple encephalitis, 2 with intracerebral haematoma, and one with an arachnoid cyst. MRI confirmed these findings.

Of the 410 patients in the isolated headache group who did not present intracranial lesions at neurologic visit, 9 patients (2.2%) were found with lesions. There were 5 children with brain tumours, 2 with hydrocephalus, one with intracerebral haematoma, and one with an arachnoid cyst. MRI confirmed these findings, and also discovered one extra case of tumour.

The remaining 400 patients presented with migraine (202 cases), tension headache (129 cases), chronic sinonasal infection (54), or were unclassified (15 children).

For neurologic examination, the sensitivity was 100% (13/13), the specificity was 97.6% (400/410), the false-negative rate was 43.5% (10/23), and the false-positive rate was 0% (0/400).

For transcranial ultrasound in the isolated headache group, the sensitivity was 75% (9/12), the specificity was 99.7% (397/398), the false-negative rate was 0.3% (1/398), and the false-positive rate was 25% (3/12).

For transcranial ultrasound in the complicated headache group, the sensitivity was 100% (13/13), the specificity was 0% (0/0), the false-negative rate was 0% (0/0), and the false-positive rate was 0% (0/13).

For transcranial ultrasound in the whole group of children, the sensitivity was 88% (22/25), the specificity was 99.7% (397/398), the false-negative rate was 0.3% (1/398), and the false-positive rate was 12% (3/25).

**Clinical conclusions**
The effectiveness analysis showed that transcranial ultrasound was associated with high sensitivity and specificity in comparison with MRI studies. Neurological examination also offered high sensitivity and specificity values, but led to a high false-negative rate.

**Measure of benefits used in the economic analysis**
The health outcomes were left disaggregated and no summary benefit measure was used in the analysis. A cost-consequences analysis was therefore conducted.
Direct costs
Discounting was not performed since the costs for each child were incurred during one year. The unit costs and the quantities of resources were reported separately. The cost analysis only included the costs of the transcranial ultrasound study and the MRI study. The cost/resource boundary adopted in the study was not reported. The quantities of resources were estimated alongside the clinical study (1995 to 1998), while the source of the cost data was not reported. No price year was given.

Statistical analysis of costs
The costs were treated deterministically.

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

Currency
US dollars ($).

Sensitivity analysis
Sensitivity analyses were not conducted.

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

Cost results
In Taiwan, an MRI study cost $300 while a transcranial ultrasound study cost $60.

All children received a transcranial ultrasound study, but only 26 children (13 in the complicated headache group and 13 in the isolated headache group) received a MRI study.

The actual costs incurred in the sample were $33,180. The costs were $28,500 in the isolated headache group and $4,680 in the complicated headache group.

If all the patients had undergone MRI studies without transcranial ultrasound studies, the estimated costs would be $126,900 ($123,000 in the isolated headache group and $3,900 in the complicated headache group).

Consequently, the strategy of performing transcranial ultrasound on all patients as a diagnostic tool in place of MRI led to overall cost-savings of $93,720 ($94,500 in the isolated headache group and -$780 in the complicated headache group).

The average per person cost-saving was $222 ($231 in the isolated headache group and -$60 in the complicated headache group).

Synthesis of costs and benefits
Not relevant as a cost-consequences analysis was conducted.

Authors' conclusions
Transcranial ultrasound was effective in diagnosing cranial lesions in children with headache. In addition, its costs were far lower than those of more sophisticated techniques, such as magnetic resonance imaging (MRI).
CRD COMMENTARY - Selection of comparators
The rationale for the choice of the comparators was clear. Neurologic examination was selected since it represents the first diagnostic assessment for children with headaches. MRI was used to ascertain the diagnostic results, as it represented the 'gold' standard. You should decide whether neurologic examination represents a valid comparator in your own setting.

Validity of estimate of measure of effectiveness
The analysis of effectiveness used a prospective case-control study, which was appropriate for the study question. All the patients underwent both diagnostic assessments, thus no randomisation was required to take into account confounding factors. The analysis was conducted on those patients who completed the one-year assessment. Those who were lost to follow-up were not included in the clinical analysis. The study sample was fairly unselected, and thus is likely to have been representative of the study population. Details on the patient demographics and study centres were reported.

Validity of estimate of measure of benefit
No summary benefit measure was used in the economic analysis. The analysis was therefore categorised as a cost-consequences study.

Validity of estimate of costs
The perspective adopted in the cost analysis was not reported. Only the costs of the diagnostic tests were included in the analysis. The unit costs were reported separately from the quantities of resources used. The overall cost analysis was not reported satisfactorily, as the source of the cost data was not reported and the costs were not analysed statistically. Further, no price year was reported, thus making reflation exercises in other settings difficult. The cost estimates were somewhat specific to the study setting.

Other issues
The authors did not compare their findings with those from other studies. Neither did they address the issue of the generalisability of the study results to other settings. In addition, sensitivity analyses were not conducted and the price year was not reported. Consequently, the external validity of the analysis was low. The study enrolled a sample of children with headache of 2 weeks' duration, and this was reflected in the conclusions of the study.

Implications of the study
The authors suggest that transcranial ultrasound is a reliable diagnostic tool for children with headache. It was also associated with cost-savings in comparison with diagnostic techniques such as MRI and cranial computed tomography. The authors highlight the relevance of transcranial ultrasound in non-Western countries where MRI and cranial computed tomography may not be available.

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