The advantages of frameless stereotactic biopsy over frame-based biopsy

Dorward N L, Paleologos T S, Alberti O, Thomas D G

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 frameless stereotactic biopsy was investigated. The technique consisted of a neuronavigation system, based on an infrared LED-based system (Easy Guide Neuro, Philips Medical Systems), and a novel stereotactic guide that was adaptable to a variety of instruments. The developed guide was freely adjustable to reach the entire cranium and would lock in place rigidly, allowing fine correction of the trajectory setting. The guide arm was fixed to a Mayfield clamp and the joints of the arm were locked simultaneously without producing tensional movement. This technique was compared with frame-based stereotactic biopsy. The stereotactic frames employed were the Codman-Roberts-Wells (Radioing) and the Resell (Elektra Instruments) systems. All biopsies were performed under general anaesthetic, induced prior to application of the base ring.

Type of intervention

Diagnosis.

Economic study type

Cost-effectiveness analysis.

Study population

The study population comprised samples of biopsies performed in patients who had undergone stereotactic biopsies.

Setting

The setting was secondary care. The economic study was carried out in London, UK.

Dates to which data relate

The effectiveness analysis was carried out between September 1996 and April 1999. The dates to which the resource use data related were not stated. The price year was not stated.

Source of effectiveness data

The effectiveness data were derived from a single study.

Link between effectiveness and cost data

The costing was undertaken prospectively on the same patient sample as that used in the effectiveness study.

Study sample

No study sample size seems to have been determined in the planning phase of the study. In addition, no power calculations were performed retrospectively. A total of 155 stereotactic biopsies were performed, of which 79 were undertaken with a stereotactic frame and 76 with a frameless biopsy. The selection of the technique for each case was

determined by the availability of the image guidance system (IGS) and the IGS research fellow. The frame-based group comprised 49 male and 30 female patients, and the mean age was 52.8 (+/- 15.9) years. The imaging modality employed to target the biopsy was computed tomography (CT) in 89% and magnetic resonance imaging (MRI) in 11% of the frame-based procedures. The frameless group comprised 42 male and 34 female patients, and the mean age was 54.9 (+/- 14.7) years. The imaging modality employed to target the biopsy was CT in 32% and MRI in 68% of the frameless procedures.

Study design
The study was a prospective cohort study that was carried out at two departments of neurosurgery (Royal Free Hospital and National Hospital for Neurology and Neurosurgery, London). The duration of follow-up was not stated, but it would appear that the patients were followed up until they were discharged from hospital. The authors did not record any loss to follow-up.

Analysis of effectiveness
All of the patients included in the study were accounted for in the analysis. The primary health outcomes used in the analysis were the radiological characteristics of the lesions, pathological diagnosis, the duration of the operations, and complications. The maximum dimension of each lesion was measured, the depth of the lesion below the nearest skin surface ascertained and the lesion classified according to the lobe(s) involved, side, eloquence and brain structure(s) affected. The duration of the anaesthetic was obtained from the anaesthetic records and the duration of surgery from the operating room computer log. Intra-operative complications were obtained from the ward record and pathology service records. There were no significant differences between the two groups in terms of their demographics, lesion site, size or pathologies.

Effectiveness results
Radiological characteristics of the lesions.

The distribution, dimensions and locations of the lesions were similar for the frame-based and frameless series. However, the depth of the lesions below the nearest skin surface was found to be significantly greater in the frame-based series (47.2 +/- 20.6 mm) than in the frameless series of cases (35.2 +/- 18.6 mm), (p<0.0001). No difference between the two groups was found in the frequency of lesions within eloquent regions.

Pathological diagnosis.

There were no significant differences in the proportions of pathologies between the frame-based and frameless series. The final pathological diagnosis was classified as high-grade gliomas (60% for the frame-based series versus 68% for the frameless series), low-grade gliomas (16% versus 8%), other tumours (13% versus 16%), inflammatory conditions (6% versus 7%) and non-diagnosed (5% versus 1%). The correct diagnosis was reached on smear examination in 130 (87%) of the 150 diagnostic specimens. These rates were similar for both groups.

Duration of operations.

For the frameless cases, the mean duration of the operation and anaesthetic was 54.2 (+/- 23.6) minutes. For the frame-based procedures, the mean duration of anaesthesia was 127.4 (+/- 31.9) minutes, whilst the mean duration of the operation was 56.3 (+/- 17.5) minutes. Thus, the mean duration of the anaesthetic was significantly longer in the frame-based series than in the frameless series, (p<0.0001). However, no significant differences were found in the duration of surgery between the two groups.

Complications.

The overall complication rate was significantly lower for the frameless series (14%) than for the frame-based series (22%), (p=0.0183). The rates of surgical complications were 6.6% (frameless) and 8.8% (frame-based), respectively. There was one fatality in each series. There were significantly more haemorrhagic complications (5 versus 0) and significantly more permanent neurological deficit (3 versus 1) in the frame-based series than in the frameless series,

(p=0.0008). There were also more infective complications in the frame-based series (10 versus 1).

Clinical conclusions

It can be concluded that frameless stereotactic biopsy resulted in a reduced anaesthetic time and fewer complications when compared with traditional frame-based stereotactic biopsy.

Measure of benefits used in the economic analysis

No summary health benefit measure was used in the economic analysis. Thus, the study has been classified as a cost-consequences analysis.

Direct costs

The resource use and the costs were reported separately. The direct costs included in the analysis were those of the hospital. These were operative procedures, ITU stay, ward stay, CT scans, MRI scans and capital costs. The cost of inpatient stay, day, surgery and imaging studies were obtained from the hospital finance department. The capital costs per case were derived for each technique by determination of the purchase costs, annual service charges, equipment lifetime and number of cases per annum. Discounting was not relevant, as the costs were incurred during a short time, and was not conducted. The study reported the average costs. The price year was not reported.

Statistical analysis of costs

The resource use and costs were treated stochastically. The statistical tests of significance employed were unpaired two-tailed t-tests (significance established at $p<0.05$).

Indirect Costs

The indirect costs were not included in the analysis.

Currency

UK pounds sterling ().

Sensitivity analysis

No sensitivity analyses were performed.

Estimated benefits used in the economic analysis

See the 'Effectiveness Results' section.

Cost results

The mean cost per case for frameless stereotactic biopsy was 6,723. This was significantly lower than the mean cost per case for frame-based biopsy (7,731), (p=0.0002). This difference arose through the significantly lower mean duration of hospital stay in the frame-based series (6.5 days) than in the frameless series (4.1 days), (p=0.0013).

Synthesis of costs and benefits

The costs and benefits were not combined.

Authors' conclusions

Frameless stereotactic biopsy is a simple, effective and intuitive technique. It has the advantages of reduced

anaesthetic time, lower cost and fewer complications when compared with traditional frame-based stereotactic biopsy.

CRD COMMENTARY - Selection of comparators

The comparator, frame-based stereotactic biopsy, was justified on the grounds that it was the current 'gold' standard technique for the retrieval of histological specimens from targets within the brain. You should decide if this represents a widely used health technology in your own setting.

Validity of estimate of measure of effectiveness

The study used a prospective cohort study, which was appropriate for the study question. However, the internal validity of the study would have been enhanced had a randomised controlled trial been used, given that this is the 'gold' standard study design when comparing different health technologies, as it minimises the potential of both bias and confounding. The study sample was representative of the study population. Both patient groups were shown to be comparable at analysis in terms of the demographics, lesion site, size, and pathologies. The analysis of effectiveness seems to have been handled credibly. However, the authors pointed out that there remained the possibility that the high rate of adverse events in the frame-based series was related to the relative inexperience of the operators (as frameless biopsy was the preferred technique in the authors' setting), whereas frameless biopsy may have been more closely supervised. The authors employed appropriate statistical tests of significance to test for any 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 therefore categorised as a cost-consequences study.

Validity of estimate of costs

The perspective adopted in the economic analysis was not explicitly stated, but it would appear to have been that of the hospital. All the relevant categories of cost for this perspective, and all the relevant costs in each category, were included in the analysis. The costs and the quantities were reported separately, which will enhance the generalisability to other settings. Resource use was obtained from the authors' setting and statistical tests of significance were performed. No further analysis of the quantities was conducted. No statistical analysis of the prices was performed. Thus, any uncertainty surrounding these variables could not be taken into consideration. The authors did not perform any discounting since all the costs were incurred during a short time. The price year was not reported, making the results of any reflationary exercises questionable.

Other issues

The authors made appropriate comparisons of their findings with those from other studies that had found similar results. The issue of generalisability to other settings was addressed, and was further enhanced by the authors reporting the costs and the quantities separately. The authors do not appear to have presented their results selectively and their conclusions reflected the scope of the analysis. The authors reported no further limitations of their study.

Implications of the study

Based on their results, the authors appear to recommend the use of frameless stereotactic biopsy over frame-based techniques. The authors pointed out that the term "frameless stereotaxy" should only be applied to methods of image guidance where the instruments are directed with stereotactic precision to a preselected target by a navigation system, and not to hand-held methods.

Source of funding

Performed within the context of the EASI project "European Applications for Surgical Interventions", which was supported by the European Commission under contract HC1012 in their "4th Framework Telematics Applications for

Health" RTD programme.

Bibliographic details
Dorward N L, Paleologos T S, Alberti O, Thomas D G. The advantages of frameless stereotactic biopsy over frame-based biopsy. British Journal of Neurosurgery 2002; 16(2): 110-118

PubMedID
12046728

Other publications of related interest
Regis J, Bouillot P, Rouby-Volot F, et al. Pineal region tumours and the role of stereotactic biopsy: review of the mortality, morbidity and diagnostic rates in 370 cases. Neurosurgery 1996;39:907-12.

Swain PD, Hitchon PW, Follett KA, et al. Computed imaging-assisted stereotactic brain biopsy: a risk analysis of 225 cases. Surgical Neurology 1998;49:640-9.

Dorward NL, Alberti O, Palmer JD, et al. Accuracy of true frameless stereotaxy; in vivo measurement and laboratory phantom studies. Journal of Neurosurgery 1999;90:160-8.

Maciunas RJ, Galloway RL, Latimer JW. The application accuracy of stereotactic frames. Neursosurgery 1994;35:682-94.

Indexing Status
Subject indexing assigned by NLM

MeSH
Adolescent; Adult; Aged; Aged, 80 and over; Biopsy, Needle /adverse effects /economics /methods; Brain Neoplasms /pathology; Female; Hospital Costs; Humans; Intraoperative Period; Length of Stay; Magnetic Resonance Imaging; Male; Middle Aged; Prospective Studies; Stereotaxic Techniques /adverse effects /economics /instrumentation; Surgery, Computer-Assisted /economics /methods; Tomography, X-Ray Computed

AccessionNumber
22002000873

Date bibliographic record published
30/04/2004

Date abstract record published
30/04/2004