PRELIMINARY ECONOMIC EVALUATION OF ELECTRICAL STIMULATION TREATMENT OF THE UPPER EXTREMITY IN POST-STROKE HEMIPLEGIA

M.J. IJzerman[1], J.R. de Kroon[1], J.J.M. Jannink-Nijlant[1], G.J. Renzenbrink[1] and J.L. Severens[2]

1. Roessingh Research and Development, Enschede, the Netherlands
2. Dept. Medical Technology Assessment, University Medical Centre, Nijmegen, the Netherlands

SUMMARY

Cost-effectiveness analysis (CEA) increasingly receives attention as reimbursement and social justification of health care expenses is considered. A preliminary economic evaluation was conducted on electrical stimulation (ES) treatment in post-stroke hemiplegia. Costs of ES treatment were estimated using a survey amongst professionals with experience with ES therapy. Benefits of ES treatment were assessed using a willingness to pay approach. Net health benefit (NHB>0: cost-saving) was estimated EURO -89.- and EURO -997.- for two commercially available ES devices respectively. Using a more progressive scenario it is concluded that ES treatment may be cost-saving if success of the treatment can be guaranteed.

STATE OF THE ART

Worldwide, the experience with technology assessment and CEAs on neuro-prosthetics in the field of physicial medicine and rehabilitation is limited. Regarding neuro-prostheses (NP) probably most experience is available on the (VOCARE) bladder stimulator in SCI (Wielink *et al*, 1997; Creasey *et al*, 2000). Both authors performed a cost-minimization analysis, i.e. they assessed the additional costs and savings after introducing the stimulator. The studies are conducted using the data collected in an uncontrolled trial in the Netherlands and USA respectively. Only direct medical costs (surgery, hospital visits and reduction in self-care and medication) were considered. In addition to the medical costs, Wielink *et al* also assessed health related quality of life (HRQoL) using the Nottingham Health Profile. The average pay back time of implanting the system was estimated to be approx. 8 years for the Netherlands (discounted at 5 %) and 5 years in the USA. In both studies it is concluded that the stimulator is economically viable.

Since the early seventies many studies have been published on the use of electrical stimulation to enhance motor control in post-stroke hemiplegia. The majority of clinical research on ES treatment of the upper extremity in post-stroke hemiplegia is still in an experimental stage. Nevertheless, a few years ago some commercial systems became available, i.e. the automove AM800 and the NESS Handmaster. The AM800 provides EMG triggered stimulation and the Handmaster is an orthosis with integrated electrical stimulation electrodes (Chae and Yu, 1999; Hendricks *et al*, 2001). Cost-effectiveness of the treatment is expected to be useful while negotiating with insurance companies about reimbursement. Sculpher *et al* (1997) argued that an economic evaluation should be designed according to the stage of clinical investigation and each of these stages requires a particular focus on economic evaluation. In the first stage emphasis is given to systematic collection of evidence on costs and effects and to collect informal clinical opinions. The second stage is more characterised by a modelling approach, whereas the third and fourth stage usually collect costing data alongside the trial. Most of the trials on electrical stimulation devices can be considered as stage II trials. Therefore, the current study was carried out to gain insight into the economic potential of electrical stimulation treatment in post-stroke hemiplegia. This paper intends to explore whether electrical stimulation (ES) treatment of the upper extremity in stroke patients can be economically viable. Although we studied both devices it is not the intention to compare them. We will focus on the best available evidence on effectiveness and on the relevant costs that are associated with electrical stimulation.

MATERIAL AND METHODS

Preliminary economic evaluation

A societal perspective was chosen for this study. The time horizon was set at one year, because it is not known what the long term effects of the treatment are. Also, it is unknown whether the subjects still use the device after a year. Because the time horizon was only one year, costs were not discounted.

Study population

Estimates of potential cost savings were obtained retrospectively from a group of experts that was expected to be able to judge the effects of electrical stimulation treatment on resources consumed. The group comprised of 7 physicians for PM&R and 7 therapists who participated in a multicentre trial on electrical stimulation therapy in stroke (response was 57 %). Willingness to pay values (benefit of treatment) were obtained from a non-experienced reference population. In this study we selected 25 workers in a rehabilitation institute (response was 76 %).

Assessment of effectiveness (willingness to pay)

A systematic literature was carried out in order to assess the effectiveness of electrical stimulation therapy in post-stroke hemiplegia (Kroon de *et al*, 2001). The review led to the conclusion that ES appeared to have a positive effect on motor control, whereas no conclusions could be drawn on improvement in functional abilities. Although EMG triggered stimulation theoretically would be more effective (Chae and Yu, 1999) this could not be established in the review. There is a moderate evidence of a larger treatment effect in a subgroup of patients with higher initial motor scores. The intermediate outcome measures that were used in the reviewed studies, typically can not be used in an economic evaluation. On the basis of the systematic review and other case studies it is expected that the effects of electrical stimulation therapy can be described as slight to moderate improvement in motor control, reduced oedema, shoulder complaints and spasticity. Assuming these effects it is possible to value the ES treatment. Valuation of the ES treatment was performed in monetary terms, i.e. cost-benefit analysis. A contingent valuation (willingness to pay) approach was used to obtain estimates of the monetary value of the treatment outcome (O'Brien and Gafni, 1996). WTP was obtained for three different probabilities (10, 50 and 100 %) of a successful outcome. Success was defined by using the results from the systematic review. The following effects were shown to the respondents: 1) reduced arm spasticity, 2) slightly less oedema, 3) less shoulder pain and a 4) moderate improvement in hand function. WTP estimates were obtained from experienced clinicians (n=8) as well as a non-experienced reference population (n=19).

Assessment of costs and resource effects

Relevant costs associated with stroke (direct and indirect medical costs and productivity loss) were determined using a database of the Health Care Insurance Board of the Netherlands (1997). Costs of the electrical stimulation treatment (therapist time and incidental and yearly cost of the equipment) were incorporated. The ES devices have an incidental cost (device) as well as yearly costs due to replacement of electrodes. Dutch market prices were used. The effects of ES on resource use (e.g reduction in medical consumption) were estimated using a standardised questionnaire. The questionnaire was send to the group of experienced clinicians. The clinicians were asked to mark the resources in which they expected a change in consumption, e.g. prescription of spasmolytics. Finally, they were asked to estimate the magnitude of the changes in resource use (percentage). Macro budgetary impact was calculated assuming that 15 % of the stroke population would be suitable for the ES treatment (mild spasticity, some voluntary activity in the hand) and that 80 % of that population actually receives the stimulation.

Data analysis

A cost model was made in EXCEL using the costing data and resource effects. Main assumption in the model is the equal distribution of costs in the population of stroke patients of interest. The estimated resource effects of each clinician were averaged and confidence intervals were calculated. Net health benefit (NHB) is calculated by subtracting the costs from the benefits (WTP) of ES treatment. A NHB>0 implies a cost-saving treatment. Sensitivity analysis is performed on the main resource parameters by using the lower and upper boundary of the confidence interval. Three scenario's were calculated: the

average scenario was calculated using the point estimates for costs and WTP, the conservative scenario was calculated using the lower and upper limit of the WTP values and costs respectively and the third (progressive) scenario was calculated in order to maximise the NHB (maximum value of WTP and most reduction in health care expenses).

RESULTS

The experienced clinicians expected that ES treatment would not reduce health care expenses, except for the use of spasmolytics (n=8) and physical therapy (n=6). Three clinicans expected a decrease in occupational therapy. Two clinicans expected a reduction in specialist consultations, the other expected that there would be more consultations.

Resource	**N^{o} hits (total: n=8)**	**Δ_{costs}**		
		Avg.	95% LL	95% UL
Spasmolytics	8	-15	-21.1	-8.9
Physiotherapy	6	-12	-16.2	7.96
Specialist consultation	3	+3.5	-26.0	32.6
Occupational therapy	3	-13	-20.7	6.0
Aids for self-care	2	-12.5	-18.0	-7.0

Table 1 Estimated resource effects (negative is reduction in costs). 95% confidence intervals are presented (UL: upper limit and LL: lower limit).

Taking into account the resource effects it is estimated that use of ES devices will increase the total costs of treatment of a stroke patient between EURO 2540.- (AM800) and EURO 3448.- (Handmaster) assuming one year of ES treatment. It appeared that the reduction in medical consumption is only marginal compared to the costs of treatment. The overall increase in cost of ES treatment is caused by electrode supplies. Yearly costs of electrodes is approx. EURO 408.- for both devices. Reduction in medical consumption does not outweigh the increase in costs due to electrodes. Costs were also calculated using the upper and lower limits of the 95% confidence intervals (table 1). Using a conservative estimation of the resource effects (upper limit, table 1) cost of ES treatment was estimated to be EURO 3967.- and EURO 3117.- for the Handmaster and AM800 respectively.

	WTP	**95% LL**	**95% UL**
100%	2451	1382	3520
50%	1708	655	2762
10%	759	151	1367

Table 2 Willingness to pay (EUROs) for ES treatment at three different probability levels.

WTP of a reference population was approx. EURO 2450.-, assuming a 100% probability of success. WTP assuming a 50 % and 10% probability was EURO 1708.- and EURO 759.- respectively (table 2).

Net health benefit was calculated using the estimates of the cost of ES treatment and the WTP values if a 100% probability of success is assumed ($WTP_{100\%}$). NHB was EURO -997.- and EURO -89.- for the Handmaster and AM800 respectively (average scenario). Using a progressive scenario ES treatment may be cost-saving (table 3).

Scenario	**$WTP_{100\%}$**	**Costs**	**$NHB_{Handmaster}$**	**NHB_{AM800}**
Average	Point estimate	Point estimate	-997	-89
Conservative	95% CI LL	95% CI UL	-2585	-1735
Progressive	95% CI UL	95% CI LL	228	1079

Table 3 Net health benefit calculated using three different scenarios.

DISCUSSION

The aim of this study was to gain insight in economic potential of ES treatment in post-stroke hemiplegia and the present study can be considered a pilot investigation in order to judge whether a full economic evaluation would be useful. In contrast to other neuroprostheses, e.g. the VOCARE bladder stimulator, it is not very likely that health care expenses will be reduced after introducing ES treatment. It is expected that only a small reduction in medical consumption (spasmolytics and physiotherapy) will be achieved whereas costs outside healthcare (absence from work) will not be relevant. Also, ES treatment requires the use of electrodes that contribute to a rise in annual treatment cost. Both ES devices use electrodes that are relative expensive compared to the market price of the device. A critical aspect in the study is that ES treatment usually requires a substantial time (e.g. 3 hours/day) investment of patients. There is an ongoing

debate about how to take the time investment into account. It is obvious however, that time investment of the patient should be incorporated in the analyses. Another critical issue is the long term use of ES devices. It is not clear if patients are long term users of these devices and abandoning ES devices may result in large costs for society without any beneficial effect.

The effects of ES treatment were derived from a systematic review, but in an economic evaluation one needs outcome measures on an aggregrate level. The most common approach is the measurement of a utility, which allows the researchers to calculate a quality adjusted life year (QALY). It is questioned whether these instruments are able to measure the effects of ES treatment. The present WTP approach is, at least in theory, more responsive to detect treatment effects. However, the approach is relatively new and not without -methodologic- discussion. For instance, WTP depends on the wages of the respondents and it is required to select a „representative sample from the general population". The amount of information on treatment effects provided to the respondents influences the outcome. For instance, the experienced clinicians had lower WTP values compared to the reference population, which may be caused by a difference in a priori knowledge about the effects. The WTP survey is difficult to complete and to overcome that problem we have chosen to include highly educated people. Although they may not represent society, it is expected that they are better suited to capture the cognitive task.

Almost 50% of the reference population values ES treatment at EURO 2451.- or higher and for those respondents, the value of ES treatment outweighs the costs. This would suggest that ES treatment may be cost-saving for a part of the respondents if the probability of success is nearly 100 %. In order to establish a high success rate it is required to critically examine the patient before an ES device is prescribed. In the present pilot it was decided to study ES treatment as a general entity and it was not the intention to compare two devices. Recently, different reviews have concluded that more fundamental research is required in order to underpin the theoretical foundations of ES treatment in general (Chae and Yu, 1999; Kroon, *et al* 2001). From that perspective it may be encouraged to improve existing knowledge on treatment mechanisms and approaches before conducting a full economic analysis.

REFERENCES

- Chae J and Yu D., Neuromuscular stimulation for motor relearning in hemiplegia. Critical reviews in PM&R, 1999; 11: 279-297
- Creasey GH, Kilgore KL, Brown-Triolo DL, Dahlberg JE, Peckham PH, Keith MW. Reduction of costs of disability using neuroprostheses. Assistive Technology 2000; 12: 67-75
- Hendricks HT, IJzerman MJ, Kroon JR de, Zilvold G., Functional electrical stimulation by means of the "NESS Handmaster" in chronic stroke patients. Clinical Rehab, 2001;15: 207-210
- Kroon JR de, IJzerman MJ, Lee JH van der and Lankhorst GJ: Therapeutic electrical stimulation to improve motor control and functional abilities of the upper extremity after stroke: a systematic review. Proc. 6th annual conference of IFESS 2001, p.155-157, Cleveland, USA
- O'Brien B, Gafni A., When do the dollars make sense? Toward a conceptual framework for contingent valuation studies in health care. Medical Decision Making 1996; 16: 288-299
- Sculpher M, Drummond MF, Buxton M., The iterative use of economic evaluation as part of the process of health technology assessment. J. Health Serv Res Policy, 1997; 2: 26-30
- Wielink G, Essink-Bot ML, Kerrebroeck PhEV van, Rutten FFH: Sacral rhizotomies and electrical bladder stimulation in spinal cord injury. Cost-effectiveness and quality of life analysis. Eur Urol, 1997; 31: 441-446
- Ziekenfondsraad. Treatment after stroke (Dutch text). Report. Amstelveen. 1997

AUTHOR'S ADDRESS

Maarten J. IJzerman, PhD, PT
Roessingh Research and Development
PO Box 310
7500 AH Enschede
the Netherlands

e-mail: m.ijzerman@rrd.nl
home page: www.rrd.nl