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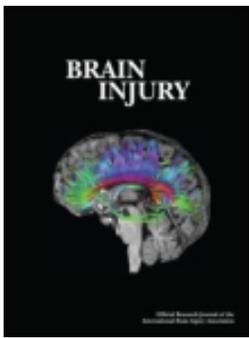
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The effectiveness of coma arousal intervention

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Thirty-one patients who were in coma or persistent vegetative state two weeks after sustaining a severe head injury were entered into a coma arousal programme. The coma arousal protocol called for a sequence of vigorous multisensory stimulations to be applied to the patient by a relative for up to eight hours a day for seven days a week. An independent study team monitored two patient outcomes, the time taken to obey a simple command on two consecutive occasions 24 hours apart and patients' score on the Glasgow Outcome Scale 10-12 months post-injury. Outcomes were compared with an historical reference group chosen from the literature, consisting of 135 similarly classified patients. Differences between the pilot study and the reference group patients on initial characteristics suggested that the pilot study patients might have the more favourable outcomes, independent of treatment effect. The sample size was sufficient to detect a 40% improvement in recovery rate. No significant improvements were noted in either the time to obey a simple command ($p > 0.2$) or in the Glasgow Outcome Scale ($p > 0.25$), although the observed difference in the latter group was 11% in favour of the pilot study patients. This study was unable to find any evidence that coma arousal, for all its arduous patient contact, had a markedly better outcome compared with conventional treatment.

Keywords: coma, outcome, head injury, rehabilitation.

Introduction

Coma arousal involves a programme of vigorous sensory stimulation designed to accelerate recovery from coma or the persistent vegetative state and to improve patients' subsequent outcome. Various independent centres in Britain and the United States administer coma arousal and proponents of the therapy claim impressive recovery rates and have argued strongly for the establishment of coma arousal units [1].

The present rate of hospitalization for severe head injury is approximately 14/100 000 per year [2]. Approximately one in ten patients with severe head injury remain in prolonged coma (patients unable to obey a simple command for periods in excess of 2 weeks) [3]. Two thirds of these patients die, become severely disabled, or continue in a persistent vegetative state one year later [4]. The potential benefits of a treatment to improve outcome in these

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patients are enormous both economically and on humanitarian grounds. Typically the severely head-injured patient has been involved in a motor vehicle crash and is a male under 30 years of age. Given the young age of most victims, the costs per case for compensation and medical care support services for the rest of life and compensation are huge. Thus treatment for such patients has a prevention priority well over what could be expected from the incidence figures.

Conventional care for head injury victims in coma and persistent vegetative state varies widely from institution to institution, and there are few guidelines as to when, for how long, and with what intensity clinicians should administer therapy [5]. Nonetheless, a belief in the benefits of early intervention after brain injury has been expressed in the rehabilitation literature [6–11] and intensive treatment schedules have been devised for the head-injured population [10, 12].

Perry has distinguished two phases in the rehabilitation of patients with neurological damage [3]. Phase 1 'preventive rehabilitation' begins soon after injury and consists of measures aimed at avoiding secondary complications such as cardiopulmonary disorders, skin breakdown, urinary and respiratory tract infections. When signs of responsiveness indicate that the patient is emerging from coma, phase 2 'comprehensive rehabilitation' is initiated to maximise the recovery of cognitive and physical functions and to teach techniques for coping with residual impairment. The latter phase usually starts with graded stimulation and involves treatment from speech, physical and occupational therapists as the patient progresses.

However, a more radical approach to the management of the head-injured survivor has been proposed. Rather than waiting until the patient has spontaneously achieved partial recovery from coma, proponents of coma arousal suggest that intensive therapy should commence while the patient is still in coma. This approach considers coma arousal therapy to be a form of comprehensive rehabilitation, with massive sensory inputs replacing the moderate stimulation usually given to patients who are in coma or persistent vegetative state. The intensity of these inputs is in excess of that suggested by Malkmus [12].

This paper describes the findings from a pilot study for a controlled trial to test the effectiveness of coma arousal in improving patient outcome. The trial did not proceed beyond the pilot phase. The design of the pilot study did not include a control group. Therefore a historical reference group of patients in an Italian study [4], which fitted entry criteria for the pilot study, was chosen to estimate the potential benefits of coma arousal as an intervention. This is the only large scale study reported for this category of patient in the literature. The outcomes described in the Italian study were similar to that reported for the same category of patient in a smaller study conducted in two Australian hospitals [3], one hospital of which was used for the present study.

Methods

Over a 15-month period between 1984 and 1985, all patients who arrived at a major teaching hospital in Sydney, Australia, with coma from a closed head injury were assessed by a study nurse. This assessment was conducted daily while in intensive care and twice weekly thereafter.

Patients in prolonged coma or persistent vegetative state (unable to obey a simple command) for at least two weeks after head injury were considered eligible for the pilot study provided there was not evidence of significant co-morbidity. There were 31 patients entered into the coma arousal programme. Only one case was excluded from the study due to co-morbidity. In addition one family refused to participate because of the poor prognosis

of the patient (who died shortly afterwards). Study subjects comprised 21 males and 10 females aged between 6 and 75 years, with a mean age of 24.

Two clinical end-points were used to assess patient outcome. The first, time taken to recover from coma, was defined as the time in days from injury until the patient was able to obey a simple command on two consecutive occasions at least 24 hours apart. This information was extracted from the daily nursing and medical reports completed on each patient. The second end-point, level of disability, was measured using the Glasgow Outcome Scale [14] 10–12 months after injury.

This latter assessment was based on the level of physical and cognitive function recorded at the time of discharge from the rehabilitation unit or from subsequent follow-up in rehabilitation outpatients or in the home. Twenty-four patients were assessed by members of the research team consisting of a neurologist, a medical epidemiologist, and social psychologist. Information on the functional status of these patients was collected from the patients and their family. For the remaining cases level of disability was determined from review of hospital in-patient and rehabilitation records (which included physical therapist and occupational therapist reports). Outcome status was assigned by the medical epidemiologist (DL) and social psychologist (SQ) after review of all relevant data on performance of activities of daily living, cognitive function and the vocational outcome. Patients were classified as having achieved either a satisfactory (good recovery and moderate disability) or poor (severely disabled, vegetative or dead) outcome.

Other clinical features of the pilot study patients were extracted from the hospital records and included Glasgow Coma Score (GCS) [15] and pupil response recorded on admission and during the worst period in the first week, presence of extracranial injuries and intracranial diagnosis (determined by review of operation and cerebral CT scan reports). The early management of patients with intracranial surgery, intubation and ventilation was recorded.

The historical reference group consisted of a consecutive series of 135 patients in prolonged coma [4]. Additional information of clinical and treatment features reported for this study was used to assess further the comparability of the two patient groups. These data included the number of patients with intracranial mass lesions and extracranial lesions, the number of patients with abnormal pupil responses and abnormal motor responses during the initial period of observation, surgical intervention and the use of intubation and ventilation for patient management.

Statistical analyses

Differences in clinical features between the groups were compared using the chi-square statistic. For 2×2 tables the test of significance incorporated Yates Correction and in cases where the expected frequency of any cell was less than 5, the level of significance was determined by Fishers Exact Test [16]. The difference between two proportions test was used to determine whether the satisfactory recovery rate differed significantly between the pilot study and the reference groups. The sample size for this comparison was sufficient to detect more than double the satisfactory recovery rate in the pilot study group compared with the historical reference group (30% versus 70%) at the 0.05 significance level with a power of 80% [17].

The coma arousal protocol

The initial protocol comprised a sequence of vigorous, multisensory stimulations lasting up to eight hours per day for seven days a week. Stimuli were applied to the auditory,

vestibular, visual and cutaneous sensory systems. Limbs were moved passively. Stimulations were delivered by close relatives of the patient. If the patient's conscious level improved, an attempt was made to increase the complexity and sophistication of the stimuli. Much emphasis was placed on stimuli with which the patient had previously been familiar. Thus favourite pieces of music were used, and the programme strongly promoted relatives as the providers of this intervention. The number of hours and type of stimulation specified in this programme is compatible with the protocols currently practised by coma arousal advocates [1]. In most cases the programme continued until the patient was accepted for conventional rehabilitation therapy.

Results

Twenty-eight (90%) of the 31 pilot study patients sustained injuries in a transport related incident. On admission 26 (84%) patients had a GCS score of less than 6 and displayed abnormal flexion, extension or no response to painful stimuli, and 15 (48%) patients had abnormal pupil responses (one or two nonreactive pupils). Nine patients had intracranial mass lesions, six were treated with intracranial surgery. All patients were admitted to intensive care and intubated and ventilated.

A comparison of the pilot study group with the reference group on important clinical variables is presented in table 1. The two groups did not differ significantly on basic injury information (intracranial mass lesions, extracranial injuries), nor on measures of injury severity (pupil response, motor response), although proportionately more patients in the pilot study group had nonreactive pupils. Management practices differed significantly between the groups. All the pilot study patients were intubated and ventilated during their stay in intensive care, while only just under half of the reference group were treated

Table 1. Comparison of early clinical features of the pilot study group and reference group of patients.

	Pilot study group		Control group		<i>p</i> value
	No.	Percent	No.	Percent	
Injury data					
Intracranial mass lesions	9	29	50	37	NS
Extracranial lesions	13	42	59	44	NS
Clinical severity at worst period					
Pupil					
non-response					
unilateral	6	19	26	19	
bilateral	9	29	23	17	NS
Motor					
no posturing	5	16	27	20	
posturing	26	84	108	80	NS
Treatment					
Intubation	31	100	116	86	<i>p</i> < 0.05
Ventilation	31	100	66	49	<i>p</i> < 0.001
Intracranial surgery	6	19	43	32	NS
Outcome					
Good/moderate	13	42	42	31	NS
Severe/dead	18	58	93	69	

similarly. Another discrepancy was noted between the two groups, namely a slightly higher mean age (29 years) among patients in the reference group than among patients in the pilot study group (24 years). However, it was not possible to test the significance of this difference because the standard deviation for age in the reference group was not given.

The first clinical end-point assessed during the pilot study was the time taken to recover from coma. The distribution of cases on the basis of time spent in coma for both groups is presented in table 2. Within each time period, the number of coma arousal patients who emerged from coma did not differ significantly from the observed in the reference group.

Since duration of coma is related to subsequent outcome [4, 18], it was expected that this lack of difference would also be reflected in the outcome results at one year. Thirteen patients in the pilot study and 42 patients in the reference group achieved the second study endpoint of a satisfactory outcome. Thus 42% of patients given coma arousal made a reasonable recovery compared with 31% in the reference group. The 11% difference in favour of the pilot study group did not reach statistical significance ($z = 1.15$, $p > 0.25$, 95% confidence interval -8% to $+29\%$).

A further consideration in assessing and adequacy of the treatment, was the extent to which the patients' relatives fulfilled the requirements of the coma arousal programme. The duration of the programme ranged from 2–32 weeks. Research on relatives' input [19, 20] in this study found that in the short term (approximately six weeks), relatives were able to maintain an average of six hours/day intensive stimulation. After six weeks the number of hours stimulation which relatives could provide decreased to about three hours/day, particularly in cases where patients had shown no marked signs of improvement.

Discussion

Patients with severe head injury who had coma arousal during a pilot study were compared with outcomes reported from a case series report from Italy. The two patient groups were contrasted on a number of important clinical and management variables which influence outcome after severe head injury [21, 22]. The age of the patients was included because younger patients make a better recovery [4, 18]. Several discrepancies were noted which may have differentially influenced patient outcomes. A statistically significant difference in the management of patients in the intensive care unit (intubation and ventilation) was identified as were possible clinically significant discrepancies in the number of patients with abnormal pupil responses and age distributions between the groups. The management profiles and the differential age distributions (the mean age being greater in the reference

Table 2. A comparison of the time spent in coma for head-injured patients treated with coma arousal with patients in the reference group.

	Patient group			
	Coma arousal		Reference	
	No.	Percent	No.	Percent
<4 weeks	9	29	34	25
4–7 weeks	7	23	21	16
>8 weeks	11	35	40	30
Dead	4	13	40	30

Chi square = 3.83, 3 d.f., $p > 0.20$.

Table 3. The relationship between the time from injury to commencement of coma arousal and patient recovery 10–12 months after injury.

Programme delay (from admission)	Level of recovery (GOS)			
	Good/Mod	Severe	Veg/dead	Total
	(n = 13)	(n = 12)	(n = 6)	(n = 31)
< 22 days	8	4	4	16
22–35 days	4	5	1	10
36–63 days	1	3	1	5

Chi square = 3.24, 4 d.f., $p > 0.5$.

group) appears to favour better recovery rates in the pilot study group which has to be weighed up against the predicted effect of finding a greater proportion of the coma arousal patients with bilaterally nonreactive pupils.

Clearly, conclusions based on such a comparison are limited. However, there is sufficient comparability between the two groups to estimate whether coma arousal is associated with markedly more favourable outcomes than is seen with conventional treatment. The sample sizes used in this comparison enable a difference of 40% in treatment outcomes to be detected as statistically significant. There was no indication from the outcomes of coma arousal patients that this intervention is associated with dramatically better outcomes observed after receiving more conventional therapy. This conclusion was the same for both study end-points, the rate of recovery from coma and the level of recovery after one year.

Sixteen patients commenced coma arousal within three weeks of admission and 15 patients commenced stimulation later. The delay for these latter patients occurred because of clinical or organizational problems (e.g., late release from the intensive care unit). Thus it could be argued that, in the pilot study, the coma arousal intervention was delayed past the time considered optimal for it to start in about half of the patients. If this were the case, and the effectiveness of coma arousal were dependent on its early implementation, then time from injury to starting the program should be related to outcome. However, the timing of the programme did not significantly predict patient outcome (table 3).

Further, it could be argued that the frequency and intensity of coma arousal offered in the pilot programme were not sufficient to achieve the claimed effects. However, the average intervention of six hours per day for a patient during the first six weeks period is far in excess of that given in conventional management and must be considered to be evidence of great dedication and interest among the relatives.

The study findings have important implications for families considering whether to become involved in a coma arousal programme, and for medical practitioners asked to comment on the relative effectiveness of such programmes. Patients given coma arousal did only marginally better than a similar group of patients treated conventionally, a result consistent with no major treatment effect. Thus our findings do not support the claim that most patients in prolonged post-traumatic coma who are given coma arousal will make a satisfactory recovery.

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References

1. LEWINN, E. B.: *Coma Arousal: The Family as a Team*. New York: Doubleday & Company Inc., 1985.
2. KRAUS, J. F., BLACK, M. A., HESSOL, N. *et al.*: The incidence of acute brain injury and serious impairment in a defined population. *American Journal of Epidemiology*, **119** (2): 186–201, 1984.
3. LYLE, D. M., PIERCE, J. P., FREEMAN, E. A. *et al.*: Clinical course and outcome of severe head injury in Australia. *Journal of Neurosurgery*, **65**: 15–18, 1986.
4. BRICOLO, A., TURAZZI, S. and FERIOTTI, G.: Prolonged post-traumatic unconsciousness: therapeutic assets and liabilities. *Journal of Neurosurgery*, **52**: 625–634, 1980.
5. EVANS, C. D.: *Aspects of recovery from physical disability after head injuries*. Presented at the symposium on head injuries held at the Royal College of Physicians and Surgeons of Glasgow, October 1977.
6. DINKIN, H.: Evaluation of disability and treatment of hemiplegia. *Archives of Physical Medicine Rehabilitation*, **28**: 263–272, 1947.
7. WYLIE, C. M.: Value of early rehabilitation in stroke. *Geriatrics*, **25**: 107–113, 1970.
8. TRUSCOTT, B. L., KRETSCHMANN, C. N., TOOLE, J. F. *et al.*: Early rehabilitative care in community hospitals: effects in quality of survivorship following stroke. *Stroke*, **5**: 623–629, 1974.
9. JOHNSTON, M. V. and KEISTER, N.: Early rehabilitation for stroke patients: a new look. *Archives of Physical Medicine Rehabilitation*, **65**: 437–441, 1984.
10. FARBER, S. D.: Neuro-rehabilitation evaluation concepts. In S. D. Farber, Ed. *Neuro-rehabilitation: A Multisensory Approach*. Philadelphia, Saunders, 1982.
11. COPE, D. N. and HALL, K.: Head injury rehabilitation: benefits of early intervention. *Archives of Physical Medicine Rehabilitation*, **63**: 433–437, 1982.
12. MALKMUS, D.: Integrating cognitive strategies into the physical therapy setting. *Physical Therapy*, **63**: 1952–1959, 1983.
13. PERRY, J.: Rehabilitation of the neurologically disabled patient: principles, practice and scientific basis. *Journal of Neurosurgery*, **58**: 799–816, 1983.
14. JENNETT, B. and BOND, M.: Assessment of outcome after severe brain damage: a practical scale. *Lancet*, **i**: 480–484, 1975.
15. TEASDALE, G. and JENNETT, B.: Assessment of coma and impaired consciousness. *Lancet*, **ii**: 81–84, 1974.
16. ARMITAGE, P. and BERRY, G.: *Statistical Methods in Medical Research*, 2nd Edition. Blackwell, Oxford, 1987.
17. COCHRAN, W. G.: *Sampling Techniques*, 3rd edition. John Wiley & Sons, New York, 1977.
18. CARLSSON, C. A., VON ESSEN, C. and LOFGREN, J.: Factors affecting the clinical course of patients with severe head injuries. *Journal of Neurosurgery*, **29**: 242–251, 1968.
19. QUINE, S., PIERCE, J. P. and LYLE, D. M.: Relatives as lay-therapists for the severely head injured. *Brain Injury*, **2**: 139–149, 1988.
20. QUINE, S., PIERCE, J. P. and LYLE, D. M.: Implementing an innovative rehabilitation program in an acute care hospital. *International Disability Studies*, **9** (4), 166–169, 1987.
21. BECKER, D. P., MILLER, J. D., WARD, J. D. *et al.*: The outcome from severe head injury with early diagnosis and intensive management. *Journal of Neurosurgery*, **47**: 491–502, 1977.
22. MILLER, J. D., BUTTERWORTH, J. F., GUDEMAN, S. K. *et al.*: Further experience in the management of severe head injury. *Journal of Neurosurgery*, **54**: 289–299, 1981.