Can behavioural observations made during the SMART assessment detect the potential for later emergence from Vegetative State?

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Abstract

The management of prolonged disorders of consciousness (PDOC) such as vegetative state (VS) is a major clinical challenge. Presently there are no validated prognostic markers for emergence from VS apart from age, aetiology and time spent in VS. This study explores whether the behavioural observation component of the SMART assessment can detect the potential for later emergence from VS. For this retrospective study 14 patients were selected who were originally assessed by the SMART as being in VS. Clinical records showed that seven of these patients have since emerged from VS (group1) and the other half remained in VS (group 2). The number, type and frequency of behaviours observed during the first five and the last five sessions of the SMART assessment were compared between the groups.

The results suggest that the patients who emerged exhibited a significantly higher number of different behaviour types than those who remained in VS (p=0.045). Finding an accurate predictor of prognosis for emergence from VS would assist in optimising the treatment and cost effective management of this population in the future. Since this is a small sample the results should be reviewed with some caution but they suggest that the patients who later emerge from VS can be differentiated behaviourally from those who remain in VS.

Key Words: prolonged disorders of consciousness, vegetative state, outcome, recovery, prognosis

Background

With the advances in acute medicine and consequently the developments in the management and care of patients with severe brain injury, there has been a significant increase in survival rates (Passler & Riggs, 2001). Many patients, however, are left in severely disabled conditions such as vegetative state (VS) or minimally conscious state (MCS). Prolonged disorders of consciousness (PDOC) represent a continuum from VS to MCS. The emergence from MCS is characterised by functional communication and functional object use (Giacino, Ashwal & Childs, 2002).

Vegetative State (VS)

The Royal College of Physicians' national clinical guidelines for prolonged disorders of consciousness (2013) defined VS as a state of wakefulness without awareness in which there is preserved capacity for spontaneous or stimulus-induced arousal, evidenced by sleep-wake cycles and a range of reflexive and spontaneous behaviours. There is no evidence of self or environmental awareness. For some patients, this is a temporary state since it is followed by some degree of recovery. However, others remain in VS and can survive in this state for many years if provided with life-sustaining treatment and adequate medical and nursing care (Jennet, 2002).

Minimally Conscious State (MCS)

The term Minimally Conscious State (MCS) was first introduced in 2002 by the Aspen Workgroup as a disorder of consciousness that describes non-communicating patients who show inconsistent, but discernible signs of behavioural activity that is more than reflexive activity (Giacino, Ashwal & Childs, 2002). Patients in MCS show some evidence of self and environmental awareness (Giacino & Kalmar, 2005; Bernat, 2006).

Differentiating between these two states is often difficult due to the nature of the changes in both central and peripheral nervous systems (Tamashiro, Cozzo, Mattei, Salierno, Rivas *et al* 2012). The management of these types of PDOC is a major clinical challenge; there is a need to establish how to best assess these patients in order to reduce misdiagnosis and increase their chances of improvement, where possible, by providing the most appropriate treatment. VS and MCS patients continue to pose problems in terms of their diagnosis, treatment and prognosis (Demertzi, Laureys & Boly, 2009).

Assessment

Levels of awareness in the PDOC patient are difficult to assess accurately. Early studies (Andrews, Murphy & Munday, 1996; Childs & Mercer, 1996) have demonstrated the challenges in diagnosing and differentiating between VS and MCS where up to 43% of patients admitted with a diagnosis of VS had been misdiagnosed. Despite numerous publications and guidelines on the diagnostic criteria of PDOC, these high rates of misdiagnosis remain unchanged, with potentially distressing consequences for patients and their families (Schnakers, Chatelle, Vanhaudenhuyse, Majerus, Ledoux *et al* 2010; Hirschberg & Giacino, 2011). However, validated scales such as SMART (Sensory Modality Assessment and Rehabilitation Technique), WHIM (Wessex Head Injury Matrix) and CRS-r (Coma Recovery Scale revised) have proved to be useful in supporting the correct diagnosis of this population group (Schnakers, Vanhaudenhuyse, Giacino, Ventura, Boly *et al*, 2009; Working Group of the Royal College of Physicians (RCP), (2013). According to a survey undertaken by the RCP (2013) these three tools are the most commonly used in the UK to assess PDOC.

Prognosis/Later emergence from VS

It is difficult to predict the outcome for patients with PDOC. This is due, not only to the complexity of this condition, but also to the biological and psychological limitation of what a person can know about the quantity and quality of another person's awareness.

Over the past decades, there has been an increase in the number of research studies into VS, its diagnosis and prognosis. Neuroimaging techniques (PET scans and fMRI) and clinical observational assessments have been widely studied in an attempt to demonstrate their potential as prognostic tools in VS (Bonfiglio, Carbonini, Bongioanni, Andre, Minichilli *et al*, 2005; Estraneo, Moreta, Loreto, Lanzillo, Cozzolino *et al*, 2013; Kang, Li, Wei, Xu, Zhao *et al* 2014; Shiel & Wilson, 2005; Tamashiro *et al* 2012; Uzan, Albayram, Dashti, Aydin, Hanci *et al*, 2003; Wijnen, van Boxtel, Eilander & de Gelder, 2007). However, the current study focused solely on whether the pattern and frequency of motor behaviours can provide valuable prognostic information regarding later emergence from VS.

According to the Multi-Society Task Force (1994), the longer the patient remains in VS the more unlikely it is to emerge from it. The probability of recovery of consciousness after 1 year following traumatic brain injury inducing VS is higher than that of non-traumatic VS (35% and 5% respectively). This probability of emergence decreases with time; however, there have been reported cases of late emergence from VS and MCS. Estraneo and colleagues (2010) reported that 20% of the 50 participants in VS recovered at least one sign of awareness between 14 and 28 months after injury. Furthermore, 24% emerged from MCS between 19 and 25 months after injury. Late recovery was significantly associated with younger age and was relatively more frequent after traumatic brain injury.

Finding an accurate predictor for recovery would be a significant development in the field of neurorehabilitation since it would assist optimising an efficient and allocating a cost effective treatment approach and management of this population group, and would aid in relieving patients' distress as well as supporting families with their concerns and anxieties.

Sensory Modality Assessment and Rehabilitation Technique (SMART)

This paper will review the data gathered from the formal SMART behavioural observation assessment. SMART is considered one of the tools of choice by the Royal College of Physicians' national clinical guidelines for prolonged disorders of consciousness (2013) when assessing patients with disorders of consciousness and making decisions regarding withdrawal of hydration and nutrition. SMART is both an assessment and treatment tool specifically designed to assess patients' sensory, motor and communicative functions when they appear to have a PDOC. SMART provides a structured and graded assessment and also a regulated sensory stimulation programme. One of the unique features of SMART is that it is conducted over a period of 10 sessions, in order to provide the patient with the best opportunity to respond over an extended assessment period, which is especially important when behaviours are likely to be inconsistent (Gill-Thwaites & Munday, 2004).

SMART includes both formal and informal assessments. The informal assessment consists of the lifestyle history questionnaire and informs. These forms gather information from family and carers regarding observed behaviours and the patient's past history. The formal assessment has two components; the SMART Behavioural Observation Assessment and the SMART Sensory Assessment. The Behavioural Observation is always conducted immediately before the SMART Sensory Assessment. The SMART Behavioural Observation assessment is a systematic observation of the patient's behaviour for 10 minutes. The type and frequency of behaviours are recorded at 10 seconds intervals throughout the 10 minute period. This enables the assessor to detect any potential functional movement that can be used later during the sensory assessment. The tool also provides opportunity for objective observation of the patients' behaviours at rest. These behaviours can then be categorised as being: reflexive (automatic response over which the patient has no control), spontaneous (random non-meaningful movements that occur without stimulus) and purposeful behaviours (meaningful intentional movements) (Gill-Thwaites & Munday, 1999). This study reviewed the range of behaviours recorded as part of the SMART Behavioural Observation component.

This study examined if the Behavioural Observation component of the SMART assessment distinguished between patients who later emerged from VS and those who did not.

Methods

For this study we selected 14 patients who were diagnosed as being in VS at the time of the assessment. All participants' diagnoses were confirmed by SMART assessment and agreed by the multidisciplinary treating team. Patients who had since emerged from VS into higher levels on the PDOC continuum, before discharge from the RHN were identified by the team and were all selected to participate in the study. There was a total of seven emerging patients identified and other seven who had remained in VS were then selected to match the emerging group on aetiology, age and time since injury. The first one, from the archived clinical records of patients in VS to match a participant in group 1 for the above criteria was included in the study. From the overall SMART assessment at the time, comprising behavioural and sensory components, there was no difference between the two groups.

Setting

This study was carried out in the profound brain injury unit at the Royal Hospital for Neuro-disability (RHN) in Putney, London. This 30 bedded unit provides assessment, diagnosis, rehabilitation and disability management of patients in PDOC.

Design

A quantitative retrospective design was used with a series of single case observational studies. Data were collected from the clinical notes of a total of 14 patients who were admitted to the profound brain injury unit at RHN and for which a VS diagnosis was confirmed and agreed by the team after completion of SMART assessment. Subsequently, group 1 had emerged from VS within 12 months of injury, whilst still under the care of the RHN allied health professionals therapists and accredited SMART assessors; and the comparison group (group 2), matched to the group 1 in age, gender and type of injury, had not emerged from VS within this timeframe.

In the early stages of VS, the SMART Behavioural Observation Assessment had been used to categorise the behaviours observed as being reflexive, spontaneous or purposeful behaviours.

Sample

As described above, seven patients who later emerged from VS (within 12 months of injury) formed group 1. The team identified these participants, as patients that had their VS diagnosed confirmed following SMART assessment and later emerged. To create equal sized groups, participants in group 2 were selected in order to match those in the emergence group with the following characteristics: age, gender, and type of injury (e.g. traumatic and non-traumatic). The criteria for inclusion in this study were:

- An initial diagnosis of VS confirmed by the SMART assessment and the team
- Emergence from VS within the first year after injury for group 1 only (and no evidence of emergence for group 2).

  This point in time was selected because the probability for recovery of awareness is very small after 3 months in non-traumatic VS or after 12 months in traumatic VS (Multi-Society Task Force on PVS, 1994).

Participants were excluded from the study if:

- VS diagnosis was not confirmed.
- The patient was not SMART assessed.
- The SMART assessment forms were incomplete.

[Insert table 1 here]

Data analysis

Data were analysed using two-tail independent group *t*-tests with a significance level set at 0.05 using version 18 of SPSS for Windows. The two-tailed test reduced the possibility of

Type 1 errors. Whilst the sample is relatively small, a *t*-test is considered robust enough. Student (1908) validated the *t*-test for small sample size. The normality of the distribution of the sample was tested using the Shapiro-Wilk test. Both sets (emerged and remain in VS) were found to be drawn from a normally distributed population (level 0.05).

The scores compared in this analysis were the total number of recorded behaviours, number of reflexive and spontaneous behaviours, number of behaviours per group, and number of behaviours observed during the first five and the last five sessions of the SMART behavioural observation assessment.

Ethical considerations

This study conforms to the World Medical Association Declaration of Helsinki. Approval for this study was given by the Ethics Committee at Brunel University and by the Research Committee at the RHN.

Results

Participants' characteristics

The group 1 patients who had emerged from VS, had a mean age of 40 years (SD=12 years, range 19-56 years). The group 2 participants who remained in VS, did not differ significantly from group 1 in age, having a mean age of 41 years (SD=12 years, range 19-52 years). The mean time since injury until SMART assessment for group 1 was 5 months (SD=2 months, range 3-8 months) and for group 2 was 8 months (SD=5 months, range 2-18 months). This difference was non-significant.

Number of behaviours

[Insert figure 1 here]

The mean number of total behaviours observed at rest in each group was examined. Examples of behaviour exhibited by the subjects in this study included head rotation from midline to the right, right foot twitch, mouth closure and lower limb adductor spasm. The mean number of behaviours for the group that later emerged from VS was 23 (SD=9), whilst for the group that remained in VS the mean was 13 (SD=8). Therefore, group 1 demonstrated a significantly higher number of behaviours than the group 2 (*p=0.045). The 95% confidence interval for the patients who emerged was [14.9, 31.6] compared to [6.2, 20] for the patients who remained in VS.

Number of reflexive and spontaneous behaviours

The SMART behavioural observation assessment enables the SMART assessor to detect any movement that the patient exhibits at rest and categorises these into three different groups including reflexive, spontaneous and purposeful.

[Insert figure 2 here]

Overall, group 1 demonstrated a higher number of reflexive behaviours (mean=10, SD=6) and spontaneous behaviours (mean=13, SD=10) when compared to the group 2 (mean of reflexive behaviours=8, SD=5.25, mean of spontaneous behaviours=5, SD=5). However, no significant difference was detected when comparing the number of reflexive behaviour between the two groups (p=0.608). Interestingly, a trend was found when comparing the number of spontaneous behaviour between the two groups (p=0.072). This lack of statistically significant differences may have been attributed to the extremely low score registered in one participant from group 1; this participant had a much lower number of spontaneous behaviours than the rest of the sample in the same group.

Movement at the beginning versus end of assessment

[Insert figure 3 here]

An analysis of the frequency of movement at the beginning (sessions 1-5) versus the end of assessment (sessions 6-10) was conducted in order to ascertain if a trend could be detected over the course of the SMART assessment. The evidence showed that the patients who later emerged from VS tended to demonstrate a slight but non-significant increase in the frequency of all their movements during the last five sessions (p=0.35, SD=162). The group that remained in VS showed an inverse, but non-significant trend (p=0.94, SD=166), i.e. the frequency of all their movements slightly decreased in the last five sessions of the SMART assessment. Whilst these differences were of interest, they were not statistically significant.

Discussion

The results from this study suggest that patients who later emerged from VS could be differentiated behaviourally from those who do not emerge. The group who later emerged from VS also demonstrated significantly more different behaviours on the behavioural component of the SMART than the ones who remained in VS. Furthermore, the frequency of spontaneous movements was slightly higher in the ones who later emerged; albeit not significantly so. This study suggests that behavioural frequency within the 10 sessions of the SMART assessment and the number of different behaviours displayed may be used as a basis for prognosis of emergence from VS.

The number of different behaviours displayed and frequencies of spontaneous movement could be an indicator of recovery, i.e. patients who exhibit a wider behaviour repertoire and higher frequencies of spontaneous movement are more likely to emerge from VS. Although not statistically significant, small differences were found in the frequency of the spontaneous and reflexive movement episodes between the two groups, with the group who later emerged showing slightly higher frequencies during the initial assessment. Further research is required to explore if significant findings can be obtained with a larger sample size.

Parallels were found with the study conducted by Wilson, Powell, Brock and Gill-Thwaites (1996). They used 24 single-case experimental studies to evaluate the effects of sensory stimulation treatment in VS patients. The response to treatment was evaluated by time sampling behaviour pre and post treatment, using the SMART Behavioural Observation component and examining for changes in behaviour that suggested increased arousal. Twelve of the 24 participants had emerged from VS subsequent to their inclusion in the study. The authors found that the group that later emerged from VS showed greater frequencies of eye opening and spontaneous movement, and at the same time the frequency of reflexive movements was found to decrease (Wilson, Powell, Brock & Gill-Thwaites, 1996).

Shiel & Wilson (2005) suggest that recovery of certain behaviours observed in the early stage may be predictive of better outcome after severe traumatic brain injury. The authors suggest that patients who show signs of early recovery of attention and cognition have greater spontaneous recovery.

Furthermore, in a study conducted by Bonfiglio and his colleagues, a decrease in the reflexive blinking rate behaviour corresponds to a significant clinical improvement measured by the Levels of Cognitive Functioning Scale score (Bonfiglio *et al*, 2005). This supports the importance of early signs of behaviours as a potential emergence indicator in VS.

These studies are all in agreement that early observed behaviours can indicate a potential for later improvement in disorders of consciousness. The current study confirmed that this finding should be further explored in order to help to determine the prognosis of this client group.

Limitations

This study had its limitations, the main one being the patients available, due the rarity of this client group. This small sample can also result in the data to be easily skewed by individual variations. However, the 14 participants were deemed to be quite representative when compared to others within the VS patient population. Without published or pilot data it is not possible to calculate the ideal sample size to measure the effect observed. This study may serve as the pilot for future studies.

In addition, due to the complexity of the client group and their medical status, a range of different medications are usually provided to address some of their complex issues. Some of these may have had some sedative effects, which may have impacted on the quality and quantity of behaviours displayed by the participants. However all the patients assessed, were medically stable and optimal to support their rehabilitation, at the time of the assessments, as this is a pre-assessment requirement in the SMART protocol.

In this study there was no follow up of the patients to ascertain who remained in VS following discharge from the specialist rehabilitation unit, and thus their diagnosis may have changed following discharge. However, after discharge from the Brain Injury Unit, two of the participants from the comparison group remained at the RHN and their diagnosis remained as VS. The other five participants were more than 12 months post-injury and therefore, according to the MSTF (1994) emergence from VS is unlikely after 12 months post-injury for traumatic brain injury and 3 months post-injury for non-traumatic brain injury.

The use of clinical notes was advantageous in that there were no demand characteristics associated with assessing patients for the research itself. However, a limitation of using available clinical notes is that the researchers have no control over their quality.

A prospective study is recommended to explore the interesting behavioural trends found, where the researchers will have control over the quality of the data and can take into account the medication being administered.

Conclusions

The issue of prognosis for recovery of awareness in the VS population is a crucial but difficult clinical determination. This study suggests that analysis of the quantity and quality of behaviours has prognostic value. If by analysing the patients' pattern and type of behaviour we will have a better understanding of their prognosis, we can be more efficient in our management and treatment approach with this population, thus ensuring resources are carefully directed. It may also help the team in making more informed decisions on possible discharge locations as well as supporting the families and their anxieties. At present there are no tools that definitively help to predict prognosis with this client group. This study identifies that the Behavioural Observation component of the SMART assessment may have prognostic value.

Word count: 3284

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Tables and Figures

Table 1 – Individual details of participants

	Age	Time since injury until admission	Type of injury	SMART initial assessment level	Current diagnosis
1	32	3 months	Hypoxic	2-3	MCS
2	45	6 months	Traumatic	1	MCS
3	50	7 months	Traumatic	1-2	MCS
4	39	6 months	Hypoxic	2-3	MCS
5	19	3 months	Traumatic	1	MCS
6	41	5 months	Hypoxic	1	MCS
7	56	8 months	Traumatic	1-3	MCS
8	35	9 months	Hypoxic	1-2	VS
9	40	10 months	Traumatic	1-3	VS
10	49	2 months	Traumatic	1	VS
11	39	6 months	Hypoxic	2	VS
12	19	18 months	Traumatic	1-2	VS
13	52	5 months	Hypoxic	1-3	VS
14	52	7 months	Traumatic	1-2	VS

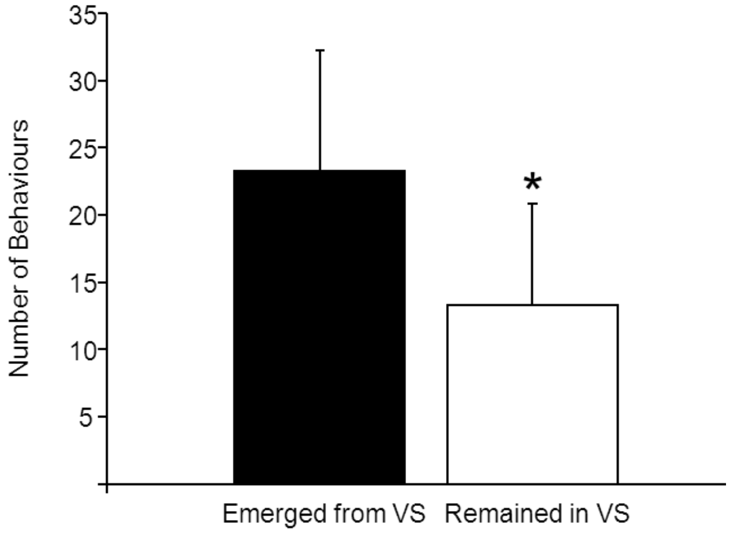

Figure 1 – Mean number of behaviours demonstrated in both groups.
Emerged from VS = 23 (SD=9); Remained in VS = 13 (SD=8) *p=0.045.

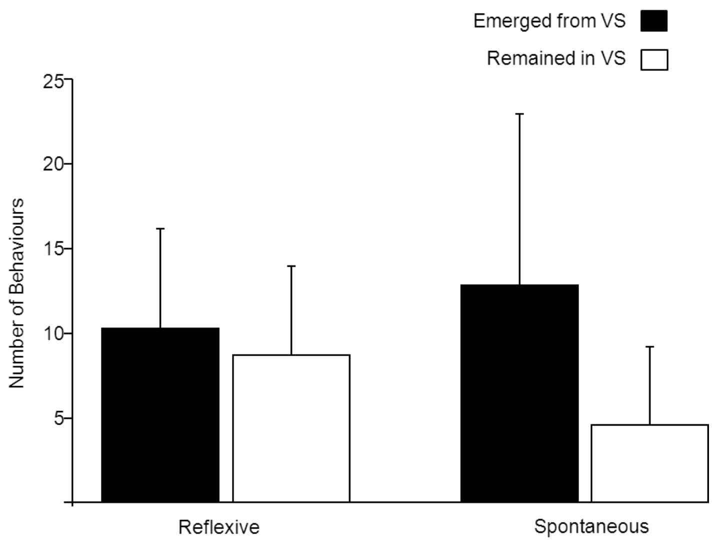

Figure 2 - Mean number of reflexive and spontaneous behaviours in both groups
Emerged from VS = 13 (SD=10); Remained in VS = 5 (SD=5) p=0.072

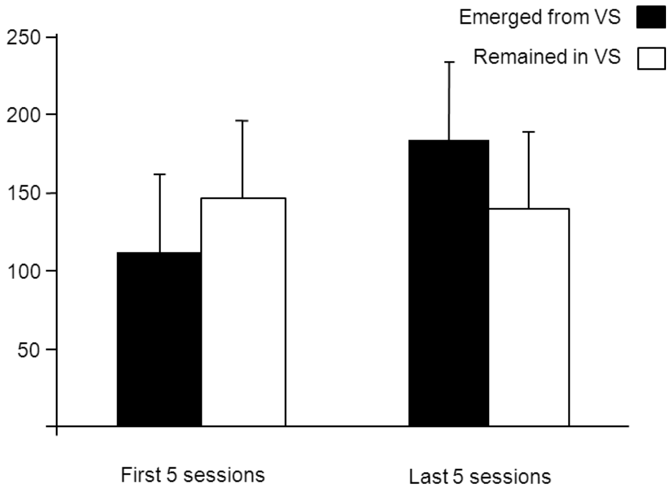

Figure 3 – Number of behaviours observed during sessions 1-5 (first 5 sessions) and 6-10 (last 5 sessions) of the SMART assessment for both groups