Real-life outcomes in spasticity management: features affecting goal achievement

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ABSTRACT

Background/objective Spasticity is a complex and common condition but there is a lack of 'real-world' data on goal setting and spasticity treatment, as well as identifying those features that might be associated with goal achievement. Our aim was to provide such data.
Methods Prospective attenders at a multi-disciplinary spasticity clinic over 2 years followed for consecutive appointments. Patient demographics and doses of botulinum toxin injected were documented. Main outcome was achievement of a primary goal but secondary goals were also recorded. Independent variables were examined for association to the outcome.
Results A total of 606 goals were set in 224 patients. The majority (75.2%) were achieved with similar levels across active (72.5%), passive (75.7%) and pain (78.6%) goals. However, in terms of the primary goal, active primary goals were achieved less frequently (59.7%) than non-active primary goal (74.2%). A logistic regression confirmed that this was the only independent variable associated with primary goal achievement. The majority of patients (61.6%) required changes to their treatment between appointments, irrespective of time since diagnosis, age or aetiology.
Conclusions Most goals set in spasticity clinic can be achieved irrespective of type of goal. However, active goals may be harder to accomplish when they are set as a primary goal. This may reflect the desire of individuals to prioritise a desirable goal rather than one that is achievable. While goal setting is important in the management of spasticity patients, very few patient or treatment factors are associated with outcome prediction. Further work needs to identify features that may predict successful outcome.

INTRODUCTION

Spasticity is a common and significant sequela of many types of brain injury including stroke, trauma, cerebral palsy and spinal cord injury. It frequently interferes with active muscle function, hence limiting potential recovery after injury.[1] Furthermore, it also affects passive function such as range of joint movement and impedes the work of carers, such as dressing, washing and transferring as well as increased risk of contracture formation and skin breakdown.[2 3]

There are several established interventions that may help with the treatment of spasticity including physiotherapy, splinting and passive stretches as well as pharmacological interventions such as oral medication or botulinum toxin. Several trials have demonstrated clear benefit of interventions, and spasticity clinics have become a regular feature of clinical practice in rehabilitation medicine and other specialties.[4–8] However, most of the evidence base is derived from small studies with highly select groups in a randomised controlled trial (RCT). Treatment in such trials is usually directed as part of the trial protocol with strict inclusion and exclusion criteria. There remains little scope for clinical judgement and variation. While RCTs undoubtedly remain the gold standard of medical research, they often do not reflect the reality of clinical practice.[9]

By contrast, there is relatively little published data on everyday real-life clinical practice or the rates of goal achievement.[10 11] The working practices of such specialised clinical services are likely to vary considerably across different populations in terms of clinician background and skills, the availability of particular treatments or therapy. Gathering and publishing such data will help to highlight such differences or similarities.

Goal setting is a key process in rehabilitation medicine practice[8 12] and introduces structure and interventions in a planned manner, in order to restore function or limit disability.[13 14] The setting of goals has benefits beyond simply motivating the patient and team; it helps to coordinate activity and interventions towards a key goal and provides the outcome measure of success.[15 16] While there are versions of measuring extent of goal attainment with a standardised score,[17 18] this takes considerable time and resource, and many clinicians simply count the achievement or otherwise of goals in a binary manner.[19]

Recent publication of a large, observational study, UpperLimb International Spasticity II (ULIS-II) Study,[3] described everyday clinical practice in a number of countries and described the achievement or otherwise of patient-centred goals. The study showed the benefit of spasticity management for patients and confirmed that the majority of patient-centred goals could be achieved, resulting in improved quality of life. However, the authors also noted considerable variation from centre to centre even within a country, a phenomenon that has been well described by others.[20] The authors called for spasticity services around the world to report on their clinical experiences preferably in larger numbers. Such reports could build up the database of spasticity knowledge, stimulate debate and discussion around aspects of service and perhaps identify the elements of 'best practice'.

Our regional spasticity centre manages a large number of individuals with spasticity of different aetiologies, treated by a multi-disciplinary team as recommended by national guidelines.[1] We wished to examine the achievement of outcomes which is based on the setting of patient-centred goals that are derived in discussion with patients, therapists and physicians. Hence the primary aim was to describe the types of goals that were set and the level of goal achievement. However, we also wished to describe differences between patients in treatment in terms of the medication that was used to treat, the particular muscles that were injected (if any) as well as total doses of treatment used. We also wished to ascertain if the treatments differed considerably from one session to the next or if it was similar. Our aims were therefore exactly the same as ULIS-II,[3] namely to describe everyday, real-life clinical practice and the achievement or otherwise of patient-centred goals.

METHODS

This is a report of real-life clinical practice. The subjects were individuals referred to a large regional spasticity centre over a 2-year period (July 2015–June 2017) attending two consecutive appointments. The first appointment recorded initial goal setting and at the second appointment, its subsequent achievement. Referrals were received from a number of sources including stroke teams, general practitioners, other physicians, therapy teams and on occasion, transfer of particularly complex patients from other spasticity services.

Patients received the routine standard of care based on national guidelines.[1] Each individual was seen by the same multi-disciplinary team made up of a consultant physician in rehabilitation medicine and a specialist neurophysiotherapist in a joint appointment. Decisions on treatment were based on discussion with the patient, carers and frequently the referring therapy team as many individuals were already under the care of a specialist therapy service at the time of referral.

This discussion resulted in setting of patient-centred goals in line with the SMART principles (specific, measurable, achievable, relevant and time limited).[21–23] Goal achievement is a validated outcome measure commonly used in many treatments particularly spasticity. Goals were divided into three types according to the classification in the ULIS studies.[11] Active goals include grasping and releasing an object, reaching for an object or carrying. Passive goals include reducing carer burden for washing and dressing, donning a splint. The third type of goal was reduction of pain or discomfort using a numeric rating scale on a rating of 0–10; an improvement of 2 scores was considered successful. Each individual had a primary goal set but there were also possible secondary goals (up to four) depending on the individual and their families' aspirations and likelihood of recovery. It was clear that, in some instances, precise goals could be set, for example, gripping and releasing an item while other goals were more generalised, for example, ability of carer to clean axilla or hand. While clinicians provided some guidance, goals were largely decided by patients and carers. Therefore they should clearly be meaningful for the individual.

As this was a description of standard clinical practice, all treatment modalities were available to clinicians including additional referral for orthotics, gait analysis or trial of functional electrical stimulation. Some individuals, often with generalised or global spasticity were treated with oral antispasticity agents while the majority required focal botulinum toxin therapy. If injected, the muscles and doses were recorded, and injections were guided by electromyography (EMG) or ultrasound. At the next visit (usually 3 months) the goals were reassessed in terms of their achievement and further goals set as appropriate with new treatment being administered. In many individuals, a similar treatment was prescribed at the next appointment but often there were changes made to the treatment in terms of the targeted muscles or doses injected. In order to calculate the proportion of individuals whose treatment is altered, a change in total dose or different muscles being targeted, was considered to be a significant change from the first appointment. Patients who missed their appointment were reappointed automatically.

For patients receiving botulinum toxin A, two preparations were used, Dysport (Ipsen) with 500 Units per vial and Xeomin (Merz) 100 Units per vial. A conversion rate of 3:1 was used to compare equivalent doses.[24 25]

Data are largely descriptive and expressed as number (%), mean (SD) or median (range) for skewed variables. For assessment of prognostic factors in the achievement of primary goal, a stepwise logistic regression model was calculated with primary goal achievement as the dependent outcome. A Hosmer and Lemeshow goodness of fit test was applied and 95% CIs for OR were calculated for the model. Although this was not a study, we used the Strengthening the Reporting of Observational Studies in Epidemiology cohort checklist when writing our report.[26]

Patient and public involvement

Patients were involved in the study from inception and are directly involved in goal setting. Patients set their goals based on their own aims and wishes. This is a description of real-life clinical practice and patients consented to their treatment and the clinic always records goal achievement as an outcome measure. There was therefore no burden or extra requirement from any patient. Similarly, ethics committee advice was taken on the reporting of routine data that are already collected as part of the clinical process and formal ethics submission was not required but consent for treatment is taken. Results will be used for each patient to help determine the type of goals set in future based on positive findings.

RESULTS

All patients attending the clinic had goals set and were monitored over two consecutive appointments. At the outset of the study this included all existing patients who were routinely attending the service for their spasticity management. Thereafter, new patients entering the service on referral were added. There were six individuals who did not attend their second appointment despite repeated efforts to reapppoint; they were not included in the analysis. Over this period, 224 patients were assessed and attended consecutive appointments. This consisted of 167 who were already in the clinic population at the outset and 57 subsequent referrals received over the period.

Mean age of the cohort was 54.4 years (SD 16.2, range 17–83) of whom 107 (47.8%) were women. The distribution of aetiology reflected the mixed nature of the real-life clinical service with the bulk of patients sustaining a stroke or intracranial bleed as shown in table 1. The group comprising 'others' was mainly hypoxic brain injury, multiple sclerosis and spinal cord injury. The time from diagnosis exhibited a wide range with median 5 years (range 0.5–66).

In terms of treatments, 105 (46.8%) were on oral antispasticity agents, 161 (71.9%) were receiving physiotherapy/occupational therapy and 125 (55.8%) had a splint.

All patients had a primary goal set and in addition, most individuals had a number of secondary goals set. In total, there were 606 goals set which were made up of 204 active, 276 passive and 126 pain related goals; these were achieved in 75.2% of all goals and 72.5%, 75.7% and 78.6% of active, passive and pain goals, respectively. Almost half (48.7%) of individuals achieved all of their set goals. However, 25 (11.2%) achieved none of their set goals.

The primary goal was achieved in 153 (68.3%) of all individuals. There seemed to be a slight preference for setting an active primary goal with 92 (41.1%) of individuals having an active primary goal set. However, individuals with an active primary goal were less likely to achieve that goal with 59.7% success compared with 74.2% with a non-active primary goal.

Out of the 224 individuals attending the clinic, 206 received focal botulinum toxin treatment. Of the remaining 18, 14 received only oral medication including baclofen and tizanidine. The mean dose of botulinum toxin A injected in each individual was 281.7 Units (SD 104.8) at the first appointment. At the second appointment, the mean dose

Table 1 Patient demographics and primary goal achievement				
	Mean (SD) or number (%)	Primary goal		X^2 or t-test, p value
		Achieved	Failed	
Age (years)	54.3 (16.2)	53.7 (16.4)	54.6 (16.1)	−0.390, p=0.697
Female	107 (47.8)	74 (48.4)	33 (46.5)	0.07, p=0.792
Aetiology				2.47, p=0.650
CVA	107 (47.8)	78 (51.0)	29 (40.8)	
IC bleed	44 (19.6)	29 (19.0)	15 (21.1)	
TBI	19 (8.5)	13 (8.5)	6 (8.5)	
CP	20 (8.9)	12 (7.8)	8 (11.3)	
Other	34 (15.2)	21 (13.7)	13 (18.3)	
Time from diagnosis (years)	7.12 (8.03)	7.28 (7.20)	6.78 (9.6)	−0.431, p=0.667
Toxin dose (U)	281.7 (104.9)	283.0 (100.7)	278.8 (114.5)	−0.941, p=0.348
Active primary goal				
Yes	92 (41.1)	55 (35.9)	37 (52.1)	5.24, p=0.022*
No	132 (58.9)	98 (64.1)	34 (47.9)	

*Significant for p<0.05.

CP, cerebral palsy; CVA, cerebrovascular accident; IC, intracranial; TBI, Traumatic Brain Injury.
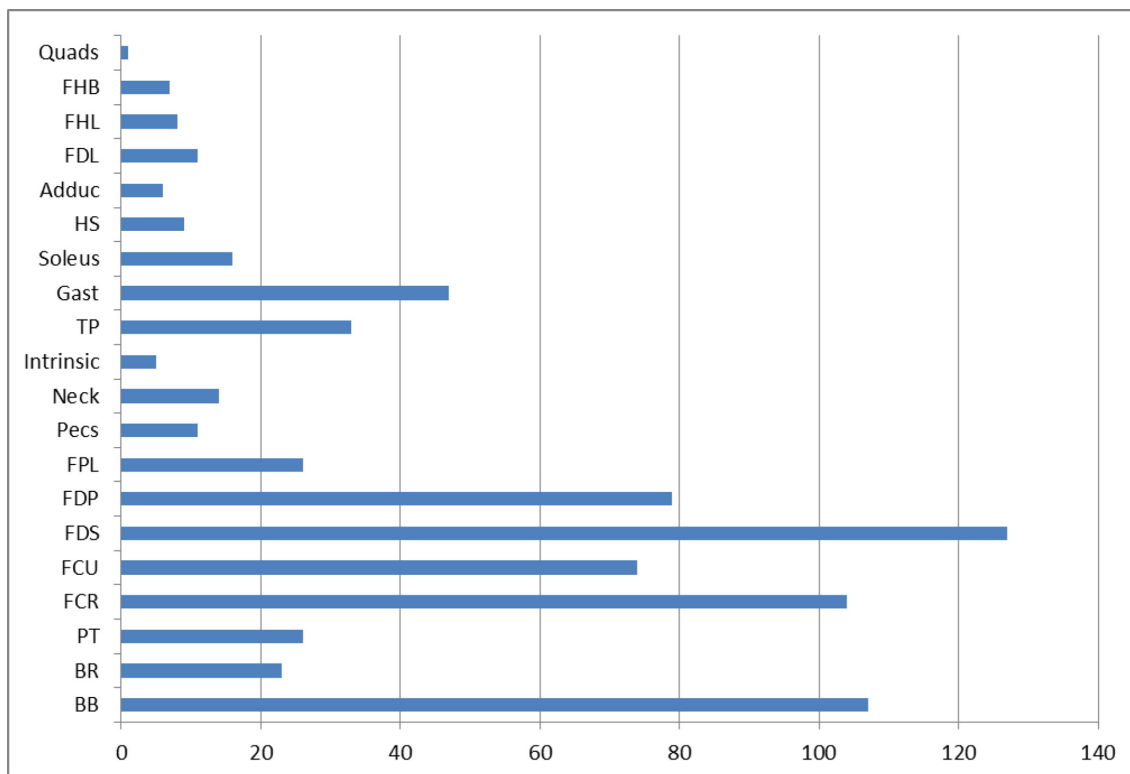
Figure 1 Muscles injected in 206 individuals. Adduc, adductor compartment thigh; BB, biceps/brachialis; BR, brachioradialis; FCR, flexor carpi radialis; FCU, flexor carpi ulnaris; FDL, flexor digitorum longus; FDP, flexor digitorum profundus; FDS, flexor digitorum superficialis; FHB, flexor hallucis brevis; FHL, flexor hallucis longus; FPL, flexor pollicis longus; HS, hamstrings; PT, pronator teres; TP, tibialis posterior.

was 256.9 Units (SD 133.7). There was a wide variation in the total amount of toxin injected as may be expected with a range of 100–600 Units. When the treatment was compared between the two time points, 138 (61.6%) individuals had a significant change made to their treatment with the remainder receiving identical or similar amounts of toxin in the same muscles. Median time between injections was 3 (2–11) months. The median number of muscles injected was 4 (1–11) and the most common muscles injected were flexor carpi radialis, flexor digitorum superficialis and the biceps/brachialis complex (figure 1).

An attempt to identify independent predictors of primary goal achievement was made using a binary logistic regression model with achievement of primary goal as the dependent outcome. The independent variables entered into the model were age, gender, aetiology, time from diagnosis, total dose of botulinum toxin injected and an active goal being the primary goal set (table 2). The model was statistically significant (p<0.001) with Nagelkerke R^2 of 0.088. The only significant factor was an active primary goal which was less readily achieved compared with passive or pain related primary goals. Hence the only independent predictor of goal achievement is the presence of a non-active primary goal.

DISCUSSION

We have shown that a regional complex spasticity clinic can set and achieve the majority of goals (75.2%) through a process of patient-centred goal setting. The similar rate of achievement of passive, active or pain-related goals implies that all types of goal are equally achievable. Primary goal achievement was less successful (68.3%) than overall goals, which may reflect the occasional insistence of an individual to prioritise their main desire or aim, even if it is felt by others that it may be difficult to achieve. This seemed to happen on occasion in the goal-setting process.

There is relatively little literature on everyday clinical practice in spasticity to compare these results with. The large multi-centre observational study. that inspired this report, found a similar rate of goal achievement. As these were in a trial setting, one may perhaps expect better results due to the extra attention focused within a study compared with everyday practice.[9] However, ULIS-II reported from 84 centres with at most, five patients at each centre.[3] The authors called for large centres to report on their findings so that a picture across regions may be built up. It is interesting that others have found that passive goals are more commonly achieved than active goals, in contrast to our own findings.[2 3 19 27] Indeed it is often suggested by clinicians anecdotally, that active goals are more difficult to achieve. In our study, while total number of active goals were similarly achieved to other types of goals, it was found in a regression model, that the setting of an active primary goal (compared with a passive or pain primary goal) resulted in lower achievement of that

Table 2 Logistic regression model of primary goal achievement

	B	P value	OR	95% CI for OR	
				Lower	Upper
Age	−0.011	0.370	0.989	0.964	1.014
Female gender	−0.101	0.746	0.904	0.490	1.667
Time from diagnosis	0.023	0.310	1.023	0.979	1.069
Aetiology		0.579			
Stroke	–	–			
Bleed	−0.463	0.280	0.630	0.272	1.459
TBI	−0.648	0.319	0.523	0.146	1.874
CP	−0.987	0.172	0.373	0.090	1.537
Other	−0.716	0.147	0.489	0.186	1.286
Toxin dose	0.001	0.532	1.001	0.998	1.003
Active primary goal	0.653	**0.030***	1.922	1.064	3.473
Constant	1.069	0.270	2.913		

*Significant for p<0.05.
CP, cerebral palsy; TBI, Traumatic Brain Injury.

primary goal. It was interesting that features such as age or time since diagnosis did not affect the likelihood of primary goal achievement.

The finding that all types of goals were equally achievable in overall terms, suggests that one type of goal should not take precedence over another. While some patients focused largely on active goals, for other individuals with more severe impairment and lack of active limb function, the achievement of passive goals is equally important in terms of improving quality of life and administration of care, for example, washing. An important part of goal setting is to educate patients about the relative importance of various goals, including those related to delivering care passively and not just function.

Treatment of spasticity varies considerably from centre to centre, let alone from country to country[20 28] and has often suffered from a lack of an easily applicable or comparable outcome measure. Indeed goal setting in itself is not a true outcome measure and surveys show considerable variation in the measures used.[28] The most commonly used tool is still the Modified Ashworth Scale (MAS) which is a relatively crude measure of resistance to movement and studies show that it is hard to demonstrate a change with interventions.[29] It also cannot produce a composite score as it is only applied for one set of muscles at a time and is generally considered a poor outcome tool.[30 31] Other measures have their particular advantages and disadvantages but the fact that so many different tools are used in so many different centres probably highlights the flaws in all of them.[1]

By contrast, a process of goal setting involving the patient, carers and their therapists is an active and vibrant process.[12 16 22] Hopefully by setting goals that are meaningful for the individual, their motivation will also be enhanced. While use of the full Goal Attainment Scale

(GAS) tool produces a validated composite score, the majority of centres prefer to use simple yes/no achievement of the goal or otherwise. Indeed only 5% of centres that use goal setting, use the full GAS tool.[19] This is probably as a result of limitation of resources in most centres; the full scoring and setting of goal attainment is a lengthy process. The lack of resources is certainly a concern in many services at a time of austerity. A balance between pragmatism and the desire to record has to be reached, as has been the case in our busy clinical service.

We have also demonstrated that the majority of individuals require a substantial change in their treatment between appointments. We deliberately chose a strict definition of new treatment so that minor changes would not constitute a change. Therefore a change in dosage >20% or a new set of muscles being injected was required to constitute a change. This highlights that even years after injury, spasticity management continues to be a dynamic process with adequate time required to evaluate and modify treatment as the clinical picture evolves. Again this is an important issue for time allocation at clinics. At our service, follow-up appointments are allocated the same time as a new patient referral to ensure adequate time for assessment and goal setting.

Our results have also shown that a large number of different muscles may be injected but that certain patterns predominate. Certainly elbow and finger flexors were the most common muscles injected, as noted by others.[3 10] We are certain that our selection of muscles and the doses injected will differ from many other expert centres. Indeed such variations have been noticed by others.[32] In another study, it was noted that one centre always injected biceps and brachialis together while another centre only seemed to inject the biceps muscle.[20] Such variations are common and provide fertile ground for discussion and

debate around the idea of best practice. As an example in our clinic, biceps and brachialis are always injected together and we rarely inject intrinsic hand muscles where our experience has found little benefit. It is reassuring that our overall doses injected and the number of muscles, is similar to that found by ULIS-II. But we are sure that some experts will disagree with some of our ideas and we welcome the debate.

We did not find any link between achievement of primary goal and features of aetiology, age and gender. Perhaps of particular significance, the time since injury was also not related to the achievement of goals. It could be envisaged that individuals with a more recent injury may have more scope for recovery and hence more likelihood of achieving their goals than those who have long standing diagnosis. We could present no evidence for this and suggest that the process of goal setting continues to show benefits many years after the initial injury. This is important as many referrals are made years after the original injury; ULIS-II found that only 40% of stoke patients were referred in their first year.

The total dose of toxin used was also not a predictor; while others have shown that dose can affect a measure such as MAS,[33 34] other studies show little effect of spasticity treatment on MAS while goal achievement and functional ability did improve.[29] It is evident that goal achievement or functional improvement are far more important than a measure such as MAS. As age, aetiology and gender had no effect on goal achievement, it seems reasonable to eliminate any bar to treatment and to openly treat all patients with spasticity, as best as possible. This has obvious implications for funding.

A number of strengths and weaknesses should be highlighted. The subjects were all seen by the same treatment team of a consultant physician and specialist neurophysiotherapist. There was therefore consistency in assessment, treatment and the process of goal setting although the latter was largely driven by the patients, carers and referring therapists themselves. The study recruited a large number of individuals with a prospective data collection and assessment. There are a number of potential problems in that patients received a differing quantum of specialist therapy and this cannot be measured although its benefits are well known.[35] While a criterion of referral is that all patients should be undergoing specialist therapy, there is extensive variation in terms of how much therapy patients were receiving. It is also known that some individuals benefit from more highly specialised input than others. The outcome measure of simple counting of goal achievement in a binary manner is admittedly a crude measure and it would have been more robust to have the full goal attainment scoring tool to provide an overall composite score if resources had allowed.

In conclusion, it has been well shown in numerous studies that patients benefit from the treatment of spasticity in a multi-disciplinary setting. The preservation of range of movement alone can prevent the development of painful contractures and decreased carer burden. In addition the opportunity to improve active movement and limb use, presents clear advantages. However, there has been a relative lack of 'real-world' clinical evidence published and the drive to publish our results was encouraged by the landmark ULIS studies which clearly showed that goals were achievable. We would call on others to report on their populations and outcomes.

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