Decision for reconstructive interventions of the upper limb in individuals with tetraplegia: the effect of treatment characteristics

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Running head: decision for reconstructive hand surgery in tetraplegia

Abstract

Decision for reconstructive interventions of the upper limb in individuals with tetraplegia: the effect of treatment characteristics.

Study Design: Survey.

Objective: To determine the effect of treatment characteristics on the decision for reconstructive interventions for the upper extremities (UE) in subjects with tetraplegia.

Setting: Seven specialized spinal cord injury centres in the Netherlands.

Method: Treatment characteristics for UE reconstructive interventions were determined. Conjoint analysis (CA) was used to determine the contribution and the relative importance of the treatment characteristics on the decision for therapy. Therefore, a number of different treatment scenarios using these characteristics were established. Different pairs of scenarios were presented to subjects who were asked to choose the preferred scenario of each set.

Results: forty nine subjects with tetraplegia with a stable C5, C6 or C7 lesion were selected. All treatment characteristics significantly influenced the choice for treatment. Relative importance of treatment characteristics were: intervention type (surgery or surgery with FES implant) 13%, number of operations 15%, in patient rehabilitation period 22%, ambulant rehabilitation period 9%, complication rate 15%, improvement of elbow function 10%, improvement of hand function 15%. In deciding for therapy 40% of the subjects focused on one characteristic.

Conclusion: CA is applicable in Spinal Cord Injury medicine to study the effect of health outcomes and non-health outcomes on the decision for treatment. Non-health outcomes which relate to the intensity of treatment are equally important or even more important than functional outcome in the decision for reconstructive UE surgery in subjects with tetraplegia.

Keywords: tetraplegia; hand function; decision-making; reconstructive hand surgery; conjoint analysis

Introduction

Subjects with a Spinal Cord Injury (SCI) at cervical level have impaired upper extremity function. Therapy for the upper extremity (UE) is most important to achieve maximal independence in ADL. Therapy for the UE of subjects with tetraplegia can be divided in three stages: the acute stage, the sub-acute stage and the reconstructive stage [1]. In the latter stage, when no further neurological or functional improvement is expected, reconstructive interventions can be considered in carefully selected subjects with tetraplegia to improve their UE function and skills. The available reconstructive interventions are reconstructive surgery with or without the implantation of functional electrical stimulation (FES) devices [2,3,4]. Since the introduction of FES implants at the end of the last century further development and application of the devices ceased because the manufacturer stopped production. Although initially good results were achieved [3], the device gained only limited popularity. This underlines that the decision whether or not to have reconstructive interventions is complex. Clinicians are often focussed on the potential effect on daily functioning of treatment, while patients also consider other factors like burden of treatment and health service delivery in their decision[5].

An understanding of the importance of both health outcomes as well as non-health outcomes for the patient is crucial in establishing shared decision making between patients and clinicians[6]. Although many preference elicitation methods exist in decision science, methods based on explicit trade offs between positive and negative aspects of treatment are preferred to opinion based techniques[5].

In the present study one such method, namely Conjoint Analysis (CA), was used for a systematic and general assessment of the importance of non-health related factors and health outcomes on the preference of patients with a cervical spinal cord injury for reconstructive UE interventions.

Methods

Conjoint Analysis

Traditionally CA has been a collective term, covering both the theory and methods of a variety of different approaches that can be used to design experiments and analyse the individual response data derived with these experiments. During the 1990's CA was introduced in the elicitation of patient preferences in health care. For an extended overview of the method, underlying theory and the application of CA in health care research the reader is referred to literature [5,7,8,9].

A CA comprises of 5 stages, including (1) identification of typical elements, also called attributes, of the therapy which is investigated; (2) assignment of various levels to the attributes; (3) design of a series of hypothetical treatment scenarios using combinations of attribute levels; (4) establishing response tasks in which the treatment scenarios are judged by respondents; (5) analysis of the response data. The stages of the present study are described in the following section.

Identifying attributes and levels

A draft version of the attributes and levels in the present study was defined by a local rehabilitation expert team and based on the literature and clinical experience. Attributes must be relevant, comprehensive and tradable. A balance must be found between the number of attributes necessary to describe treatments and the feasibility of the decision task. Although FES was not an actual treatment option at the time of this study it was included in order to assess the desirability of implanting medical devices on the preference for treatment. Some of the “none options” formulated in the levels, e.g. for risk of complications, may be clinically unrealistic, yet they are methodologically important to access trading between attributes and levels. The draft version of attributes was adapted after being reviewed by five (international) experts. After a pilot test in six SCI subjects a final version was applied in the present study (Table 1).

The CA response task

A choice-based CA software package by Sawtooth Software™ * was used to design the treatment scenarios. Seventeen sets of two scenarios were randomly composed for each subject using the minimal overlap method.

With this type of CA the occurrence of equal levels for one attribute in both treatment scenarios included in the response set is limited to a minimum. The choice-based CA also allowed calculation of main effects of attributes and levels at group level. Subjects were asked to select the scenario in each set which they would prefer if they were considering upper extremity reconstructive therapy. For an example of a choice set see Figure 1.

Internal validity and consistency

Three fixed choice sets were included in the response task. The first composed a positive scenario with all levels set at minimum opposed to a negative scenario with all levels set at maximum. The second and third presented identical scenario's in a reversed order (the mirror set). Subjects were expected to choose the positive scenario as well as the same scenario twice in the mirror sets. Inconsistent subjects were excluded from final analysis.

Research setting and patient selection

Potential subjects were selected from the outpatient records of seven rehabilitation centers in the Netherlands, specialized in the treatment of spinal cord injuries (SCI). We certify that all applicable institutional and governmental regulations concerning the ethical use of human volunteers were followed during the course of this research. The inclusion criteria were a motor complete C5, C6 or C7 SCI, according to the guidelines of the American Spinal Injury Association (ASIA) [10], with at least one arm classified as motor group 1 to 4 according to the International Classification for Surgery of the Upper Limb in Tetraplegia[11]. The motor groups are listed in table 2. This classification also determines sensory function of the hand which is important for actual planning of surgery in individual patients but was not considered as an exclusion criterion for expressing preference for treatment. Subjects had to be medically and neurologically stable, at least one year after the initial injury, and they should be potential candidates for surgical reconstruction of elbow extension and palmar and/or lateral grasp function based on their motor function. Subjects were excluded if they previously had surgery to improve UE function, or if they profusely had declined reconstructive treatment in the past. After informed consent, one of the authors (JvT) visited the subjects at home. Gender, age, time since injury, and SCI and UE classification according to the guidelines were established. General and standardized information about UE reconstructive surgery was provided with a PowerPoint presentation and oral explanation. The information was not tailored to the actual clinical status of the patients but described surgical possibilities in a general manner. Information, based on actual state of the art[2,4], was given about following topics:

- The possibility to improve active elbow extension and the importance or even prerequisite of elbow extension for proper use of improved hand function.
- The possibility to improve key and palmar grasp.

- The need for and extent of preoperative screening.
- The surgical procedures necessary for treatment.
- The need for postoperative splinting and inpatient and outpatient rehabilitation.
- The risks of postoperative bleeding, infections and adhesions, which could have a negative effect on functional results, were mentioned in general terms as possible complications.

After finalization of the CA response task questions of patients about individual possibilities for UE surgery were answered and they were asked if they would consider such an intervention in the near future.

Data analysis

Calculation showed that data of 50 subjects were required to obtain sufficient statistical power. Multinominal logit regression analysis was used to calculate regression coefficients for each level of all the attributes. Attributes where the difference, tested with a t-test ($p<0.05$), between maximum and minimum regression coefficient was significant contributed to the overall decision for treatment.

The relative importance of the attributes, which represents the influence of an attribute compared to the other attributes, and the relative preference for each level within an attribute compared to the other levels of the same attribute were also calculated.

The hierarchical Bayes analysis module of the Sawtooth Software™ package was used to calculate the relative importance of the attributes for each individual subject. An arbitrary cut off of 30% was used to determine whether a subject had a dominant preference for one attribute in the decision for treatment (relative preference of 0.30 or above for any of the including attributes).

Results

A total of 57 subjects were selected, four could not be reached or declined from participation. Characteristics of the 53 participants are presented in Table 3. Four subjects were considered inconsistent in their response and omitted from the CA analysis.

The results of the analysis are shown in Table 4. On a group level, all attributes significantly contributed to the decision to undergo reconstructive intervention therapy ($p < 0.01$ for all attributes). Figure 2 shows the relative importance of the attributes and their 95% confidence intervals. The inpatient rehabilitation period, the type of intervention, the number of operations, the time spent in cast and, the risk of complications are either more important or of the same order of importance as functional outcome at hand level. Only the outpatient rehabilitation period is deemed less important than functional outcome in the choice for treatment. In the individual analysis, 29 of the 49 (59.2%) subjects included considered all attributes important in the decision for treatment. Implantation of a FES device was absolutely rejected by 8.2% (these subjects never choose a scenario containing a FES device). Dominant preferences were identified for: intervention type 12.2 %, number op operations 6.2%, inpatient rehabilitation time 8.2% and results hand 6.2%.

Figure 3 shows the preferences for the levels within each attribute. In general, the distribution over the levels is as expected with the best or most attractive levels having the highest preference. Of the patients interviewed 29 (52 %) indicated to be interested in reconstructive surgery.

Discussion

Technical innovations in health care are developing rapidly, and also spinal cord medicine is confronted with many new opportunities[12,13]. In the development, application and evaluation of new techniques the opinion of the public and/or patients is increasingly considered to be very important.[9] This is emphasized by the fact that studies show differences in clinician and consumer preferences with respect to health outcome and non health outcome factors of therapeutic interventions[14]. The assessment of acceptance of new technology by patients should therefore not be based on functional outcome alone.

The present study focussed on the decision on different types of reconstructive UE intervention in tetraplegia. All attributes investigated in the present study contributed significantly to the preference for reconstructive UE intervention and should be taken into account when subjects are informed about these therapies. Attributes related to the intensity or "burden" of therapy are equally important, or even more important than functional outcome characteristics in deciding about therapy. However, a large inter-individual variation in the relative importance of the attributes was found and over 40% of the subjects focused on one specific treatment characteristic. Clinicians should be aware of the possibility that in clinical situations, although all aspects of treatment are discussed as is standard in good clinical practice, some patients do not consider all relevant information. For instance, although scientifically proven and favoured by professionals as a very rewarding procedure [15] the potential benefits of active elbow extension seem to be underestimated by a considerable number of potential recipients of surgical UE reconstruction in this study.

Tendon transfer alone is preferred to tendon transfer combined with electrical implants. However, only 8.2% of the subjects absolutely rejected the implantation of devices. Although the studies by Rushton and Gorman et al. showed that only a minority of potential candidates for a FES device actually choose for implantation [16,17] this might not be a result of the implantation of foreign bodies, but rather because of the combination of uncertain potential benefits and treatment burden.

Subjects seems to prefer one operation over two operations but no preference is expressed for the location at which the post-operative period, while the operated arm is immobilised in a cast, is spent This might be explained by the uncertainty that patients face as a result of a temporary increased dependency. The length of outpatient treatment was found to be relatively unimportant, except for the longest period of 12 weeks, which was highly unappreciated.

An appropriate choice of attributes and levels is crucial in a CA study. The attributes and levels included in this study were based on the literature and reviewed by international experts. Additionally, a selection procedure of attributes was necessary to keep the response task manageable for patients. As a consequence, conclusions can only be drawn in relation to the attributes included in this study. For instance a more active “flexor-tendon-injury-type” rehabilitation protocol which is recently brought into discussion[18]cannot be evaluated based on the results of this study.

Obviously, the subjects in the study population represent a range of upper extremity functions and functional capabilities. However, the main objectives of surgical intervention for patients with an arm classification of M1 to M4 are active elbow extension and restoration of one or two grasp functions [2,4] . In this respect, the sample is adequate for the purpose of this study, and the subjects should be capable of weighting the importance of the selected attributes in decision making for surgery on a general level.

The present study focused on a group of subjects in a stable condition who had their SCI for a longer period of time. A total of 29 subjects (52%) showed interest in reconstructive interventions for themselves. However, in clinical practise only a minority of suitable subjects actually decide to be operated. Research has shown that, in determining life satisfaction in patients with long lasting SCI, psychological and social factors are more important than the severity of the injury [19]. In the initial rehabilitation period, however, self-care goals are frequently considered to be most important by the patients[20]. Improvement of upper extremity function can contribute to achieving these goals. It would be interesting to see if preferences for therapy and the importance of treatment characteristics change over time, and differ in patients with a recent SCI. This needs to be investigated as the results could be beneficial in the discussion about the timing of the intervention.

In conclusion, this study demonstrates that it is important to consider both health and none health factors in the decision for treatment of the UE function in patients with tetraplegia. With regard to reconstructive UE interventions subjects with tetraplegia attach equal importance to non-health outcome factors indicating the intensity or burden of the treatment as to improvement on hand or elbow function in determining the preference for treatment.

The provision of state of the art information and an individual approach are essential in considering the planning of surgical therapy and postoperative rehabilitation. Clinicians should be aware of the various elements which determine the motivation of patients and the fact that a considerable number of patients are focused on limited aspects of treatment.

The present study emphasizes the importance of research into the factors that influence the motivation of patients to choose a treatment. Results of such studies can be used to guide further development and practical application of new technology for further improving of the outlook of patients with a spinal cord injury.

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***Address for the Conjoint Analysis software program used in the study:**

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Titles and legends to figures

Figure 1. Example of scenario set

Figure 2. Relative importance and 95% confidence intervals of attributes.

Figure 3. Proportion or relative attractiveness of the levels (for a description of the levels see Table 1)

Table 1.

Attributes and levels

1. Intervention	a. Tendon transfer
	b. Tendon transfer + FES system implantation
2. Number of operations & time +location spent in a cast	a. 1 operation; 3 weeks cast as inpatient
	b. 1 operation; 3 weeks cast at home
	c. 2 operations; 2*3 weeks as inpatient
	d. 2 operations; 2*3 weeks at home
3. Rehabilitation period as inpatient	a. none
	b. 4 weeks
	c. 8 weeks
	d. 12 weeks
4. Rehabilitation period as outpatient	a. none
	b. 4 weeks
	c. 8 weeks
	d. 12 weeks
5. Risk of complications	a. none
	b. 1 in 50 (2%)
	c. 1 in 20 (5%)
	d. 1 in 10 (10%)
6. Functional result elbow	a. Active extension after intervention
	b. No active extension (no intervention)
7. Functional result hand	a. Moderately improved key grip
	b. Moderately improved key and palmar grip
	c. Very much improved key and palmar grip

The short statements concerning the last two attributes were described in slightly more detail to the subjects. Active elbow extension was described as the possibility to extend the elbow against gravity, overcoming slight resistance. Moderately improved grip was described as considerably stronger than in the pre-operative situation, making it possible to pick up objects such as a plate, cutlery, videotape, ADL equipment, etc. Very much improved hand function was described as very much stronger grip than in the pre-operative situation, making it possible to pick up heavier objects such as like tools, phone books, etc. For description of risks see text.

Table 2.

Motor Groups according to the International Classification for Surgery of the Upper Limb in Tetraplegia

Motor group (each mentioned muscle has at least strength grade 4 MRC)
0 No muscle below elbow suitable for transfer
1 M. Brachioradialis
2 M Extensor Carpi Radialis Longus plus above muscle
3 M Extensor Carpi Radialis Brevis plus above muscles
4 M. Pronator Teres plus above muscles
5 M. Flexor Carpi Radialis plus above muscles
6 Finger Extensors plus above muscles
7 Thumb extensors plus above muscles
8 Digital Flexors plus above muscles
9 Lack of Intrinsic Muscles only
X Exeptions
M.Triceps is assessed and noted separately

Table 3.

Demographic data of the study population

Male	Female	Mean Age (sd)	M0 R/L[1]*	M1 R/L	M2 R/L	M3 R/L	M4 R/L	M5 R/L	TSI[2] 1-2	TSI 2-5	TSI 5-10	TSI > 10
41	12	39 (10)	1/2	14/12	11/12	8/6	15/14	4/7	1	10	13	29

sd: standard deviation;

[1] number of arms at the right (R) and left (L) side classified as motor group M1 to M5 according to the International Classification of the Upper Limb in Tetraplegia. Eight of the subjects with one arm classified as M4 had bilateral M4 classification, and one had the other arm classified as M5. In all other subjects with one arm classified as M4 or M5, the opposite arm was classified as M1, M2 or M3.

[2] Time since injury in years

Table 4.

Results of conjoint analysis

attribute levels[1]	Effect[2]	S.E.[3]	Dif.[4]	Pld.SE.[5]	T[6]	p[7]
intervention						
tendon transfer	0.28	0.04	0.57	0.06	9.82	< .01
tendon transfer+FES	-0.28	0.04				
no. op.and time/loc. in cast						
1 op; 3 wks cast; inpatient	0.33	0.09	0.65	0.12	5.32	<.01
1 op; 3 wks cast; at home	0.24	0.08				
2 op; 2* 3 wks cast; inpatient	-0.32	0.09				
2 op; 2*3 wks cast; at home	-0.25	0.09				
inpatient rehabilitation						
none	0.53	0.10	0.91	0.13	7.10	<.01
4 weeks	0.16	0.09				
8 weeks	-0.31	0.09				
12 weeks	-0.38	0.09				
outpatient rehabilitation						
none	0.14	0.09	0.34	0.13	2.70	<.01
4 weeks	-0.04	0.09				
8 weeks	0.10	0.09				
12 weeks	-0.21	0.09				
complications						
none	0.32	0.09	0.66	0.12	5.41	<.01
1 in 50 (2%)	0.02	0.09				
1 in 20 (5%)	-0.01	0.09				
1 in 10 (10%)	-0.33	0.09				
effect elbow						
active extension	0.21	0.04	0.41	0.06	7.00	<.01
no active extension	-0.21	0.04				
effect hand						
moderately impr. key grip	-0.32	0.07	0.61	0.10	6.40	<.01
moderately impr. key + palm. grip	0.03	0.07				
very much impr. key + palm. grip	0.29	0.07				

[1]For exact description of attributes and levels see Table 1. [2] Coefficient in logit regression analysis; [3] standard error; [4] difference between coefficients of levels with maximum and minimum effect per attribute; [5]pooled standard error; [6] t-value; [7] p-level.

For further explanation see text.