DOCTORAL SCHOOL OF HEALTH SCIENCES

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QUALITATIVE AND QUANTITATIVE FACTORS AFFECTING THE LIFE QUALITY OF CONGENITAL TALIPES EQUINOVARUS PATIENTS

Ph.D. Thesis

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Pécs, 2018.

Introduction

Congenital talipes equinovarus (CTEV) is a common developmental disorder of considerable medical and social importance, whose treatment has only been partially successful up until recently. The European prevalence of the condition is approx. 1-2 per mil and the data of Hungarian Birth Defect Registry indicate a prevalence of 1.18 per mil between 2004 and 2009, which means an average of 116 new cases annually (Bohner-Beke, 2012).

Lately the international literature has mostly focused on the aetiology and treatment of the condition, as well as the functional results and effectiveness of the Ponseti method (Porecha, 2011; Duffy, 2013). When two different treatment methods are compared, the basis of comparison may prove to be challenging; similarly, who is supposed to determine the function of the lower limb – the doctor or the patient? It is also important to note who determined the effectiveness and what methods were used to compare the results.

Specialists are divided by the methods of treatment, while researchers differ along the lines of objective and subjective assessment. As a result of scientific evidence, today the first line treatment is the Ponseti method and patients' subjective assessment of the functional result has gained more importance. The first method of correction, developed by dr. Kite, involved extensive casting and surgery of the soft tissues. Ignacio Ponseti modified this technique by focusing on the manipulation of the talonavicular joint as part of the casting. Surgical intervention has been minimised to cutting the Achilles tendon, and a special orthosis (Denis-Browne splint) has to be worn for half a year (Kiss, 2014). The first Hungarian reports of the Ponseti method were published by Sohárt, Gellért (2012), Szőke, György (2014) and Kiss, Sándor (2014), who applied the Pirani scoring system when assessing the effectiveness of the intervention.

In chronic conditions, there is an increasing number of Hungarian quality of life measurement tools that researchers can use; however, as regards CTEV there are no general and disease-specific quality of life questionnaires that could be used in the assessment of patients (Móok, 2014; Rigó, 2014; Minkin, 2014). Information on patients' health and quality of life would be essential, though as the review of the international scientific literature justifies its role in the evaluation of treatment efficiency and comparison of treatment results.

Objectives

The aim of my thesis was to list and examine factors that influence the quality of life of CTEV patients. When examining the qualitative factors, we get insight into the patients’ subjective experience of a congenital anomaly, which – in spite of being localised – is present throughout their whole life and has a significant effect on it. The answers can be examined from the different perspectives of the various disciplines affected and we do aim to emphasise the multidisciplinary nature of the issue. Besides attempting to separate the individual aspects, we also tried to synthesise the results and investigate their relationship. When examining the qualitative factors that influence the quality of life, we used various questionnaires to get to know the individual, subjective assessment of our patients. Of the objective factors that influence the quality of life, we measured lower leg atrophy, which is easy to examine and closely related to function, therefore it is reported as a quantitative factor. Following the analysis of these two areas, we tried to find a relationship between the objective and subjective factors in order to get a more comprehensive picture of the quality of life of CTEV patients. Our final objective was to formulate some practical messages for specialists dealing with this condition so that we can make up for the relative lack of Hungarian scientific literature covering this field.

Hypotheses

Health sciences:

1. As regards qualitative factors, the general health status of CTEV patients is worse than that of the Hungarian population, especially concerning ‘Agility’ and ‘Pain/ malaise’.
2. As a result of the special anomaly that affects the lower limb, it is worth supplementing the general health quality measurement tools with a specialised tool, as this latter instrument better characterises the health quality of CTEV patients, but the two tools are interrelated.
3. As for the quantitative factors, there is an objective measure that is characteristic of patients’ health, thus serving as an important feature of CTEV patients’ quality of life.

Psychology:

4. The subjective self-assessment of CTEV patients is related to both the general and the disease-specific quality of life.
5. As regards age groups, the self-assessment of adolescent patients shows greater variability.
6. Patients with unilateral CTEV tend to have lower self-esteem than those with a bilateral deformity as the atrophy of the affected limb results in a clear difference between the two legs.

Sociology:

7. By examining six soft variables we can determine the fields in which CTEV patients consider themselves disadvantaged, and four hard variables influencing the quality of life can also be allocated to this sociological investigation.

Materials and methods

1. Examination of qualitative factors

Study group

For the study purposes, we recruited patients from the Department of Orthopaedics at the Medical School of the University of Pécs. The study protocol was approved by the Regional Research Ethics Committee of the University of Pécs (PTE/40288/2017). As a result of the three different questionnaires we used we needed three age groups, and altogether we examined 75 participants (61% males, mean age: 12.45 years, 2–44 years).

Group 1 consisted of 38 children aged 2–11.99 years (50.7%). As they cannot evaluate their quality of life, in this group we used indirect data gained from the parents.

Group 2 included 20 children aged 12–17.99 years (26.27 %). They are capable of commenting on their own quality of life, but parental report was also recorded.

Group 3 consisted of 17 adults (22.7%) aged 18–44 years (mean age: 26.59 years); they evaluated their own quality of life.

We used different methods to study the three disciplines:

Method (1): Studying the life quality of CTEV patients from the perspective of health sciences with a general and a disease-specific life quality questionnaire.

We used the self-completed EQ-5D (EuroQol) questionnaire to study the general health status of patients as this tool can be used in any conditions. It has two parts, the EQ-5D utility index and the EQ-5D Visual Analogue Scale. In the first version of the questionnaire - EQ-5D-3L - three possible answers (no problems, some problems, serious problems/ unable) could be given to questions examining five dimensions (mobility, self-care, usual activities, pain/ discomfort and anxiety/ depression). The questionnaire has a validated Hungarian version as well, which can be used following registration with the EuroQol Group (https://euroqol.org). The instrument has an extensive scientific background, and it has enabled us to compare health status changes that patients experience in diverse medical conditions (Péntek, 2007; Baji 2015). As regards disease-specific questionnaires, the choice was obvious as the most commonly used research tool is the 'Disease Specific Instrument' (DSI) developed by Roye et al. This instrument is a simple, validated and tested disease-specific tool that was designed to assess 10 items in order to measure the outcome of the treatment as well as overall satisfaction, appearance, pain and physical limitations. To be able to use this instrument, we needed the author's permission and validation. The process consisted of the following steps: 1. obtaining permission; 2. translation; 3. back-translation; 4. author's approval of back-translation; 5. sending out the approved questionnaire; 6. psychometric testing (Lovas, 2002).

The DSI has 10 items and two sub-scales, which are satisfaction and function. The 5 items of the satisfaction subscale are the following: (1) satisfaction with the status of the foot, (2) satisfaction with the appearance of the foot, (3) teasing, (4) finding shoes that fit, (5) finding shoes that they like. The items of the function subscale: (6) pain in the foot; (7) limited ability to walk; (8) limited ability to run, (9) pain during heavy exercise, (10) pain during moderate exercise (Dietz, 2009).

Method (2): Studying the life quality of CTEV patients from the psychological perspective with the Rosenberg Self-esteem Scale.

The scale has 10 items, 5 of which are positive and another five are negative statements dealing with the respondents' general feelings about themselves (Sallay, 2014). The validity of the scale has been confirmed by several studies and it is widely used (Rózsa, 2014; Urbán, 2014).

Method (3): Studying the life quality of CTEV patients from the sociological perspective with a self-compiled ad hoc sociological questionnaire.

The questionnaire consists of 9 closed and one open-ended question. We were trying to identify affected areas by examining 6 soft variables (disability, free time activities, income generation, personal relationships, acceptance, achieving aims) and 4 hard ones (age, gender, residence, affectedness).

Methods of statistical analysis

Softwares Microsoft Office Excel 2016 and SPSS 22.0 were used for analysing our data, and the level of statistical significance was $p \leq 0.05$.

We used the Mann-Whitney test to analyse significant differences and Spearman rank correlation to measure the strength of statistical relationship. The comparison of the different questionnaires necessitated a uniform approach; therefore, percentage values were rendered to the scales and 100% meant full satisfaction.

Results

Method (1) Life quality from the perspective of health sciences – results

Results of the EQ-5D-3L questionnaire

EQ-5D indices were based on the British utility weights. By applying the code of the answers to the 5 dimensions we calculated the mean value of the EQ-5D index to be 0.89 (n=37, min=0.27; max=1.00, variance=0.17), while the mean value of the EQ-5D Visual Analogue Scale was 79.92. The distribution of the answers suggests that the most significant decrease in the general health status of CTEV patients can be detected in the ’pain/ discomfort’ and ’usual activities’ dimensions. No significant differences were found between EQ-5D index values and age, gender or affectedness.

Results of the DSI

When adapting the DSI, we prepared three different versions which were identical content wise: we compiled a questionnaire for parents (proxy), children and adults (Bohner-Beke, 2018). In the case of Group 2 both the children and their parents commented on participants’ quality of life so that we could compare the answers. When assessing the mean value of the individual DSI items in this group, we found the most significant decrease in quality of life in items ’foot pain’ and ’finding shoes that fit’.

Results of analysing the differences between proxy and self-questionnaire answers in Group 2 (n=20)

Regarding the two subscales, the children and their parents gave contrasting answers and the patients’ assessment of their child’s quality of life is 6.49 points higher than that of the children. Parents are less satisfied (-2.1 points), especially with the appearance of their children’s foot (-5.26 points), but they tend to give better functional points (+15.09), which is mostly the result of misevaluating pain severity (+10.53 points). Apart from these differences, the high Spearman rank correlation coefficients suggest a significant relationship between the 2 sets of subscales and also the 2 complete scales.

The self-completed DSI questionnaires (n=37) showed a significant difference between two age groups in item 6 ’foot pain’ (U=117.00; Z=-2.173; p=0.030), as those over 18 reported less foot pain.

The parental (proxy) DSI questionnaires (n=58) showed significant differences between the age groups in 6 out of 10 items, the complete DSI (U=173.00; Z=-3.189; p=0.001) and its 2 subscales. Altogether, the parents of children aged 2–12 years reported better quality of life.

Regarding item 1 ’satisfaction with foot status’ (U=234.50; Z=-1.951; p=0.050) and item 3 ’teasing’ (U=250.50; Z=-2.047; p=0.040) there was a significant difference between the genders: girls’ parents were more satisfied.

We also found a significant difference between 5 items of the proxy DSI questionnaire, its two subscales, the complete scale (U=213.50; Z=-2.622; p=0.009) and treatment method: parents of children treated with the Ponseti method showed higher satisfaction.

Results of external validity examination (n=37)

The Spearman rank correlation was used to test the relationship between items of the DSI and the individual dimensions of the EQ-5D questionnaire, and we found high correlation coefficients (rs>0.6), which proves the interdependence of the individual items, subscales and dimensions of the two tools. Overall, the EQ-5D index showed the highest correlation with item 7, ’limited ability to walk’ (rs=0.88, p<0.001) and the lowest with item 6, ’foot pain’, but even this latter correlation was of moderate strength.

Method (2): Life quality from the perspective of psychology – results

The individual items of the Rosenberg Self-esteem Scale can be allocated 1–3 points each, thus the maximum score is 30, and CTEV patients had a mean value of 22.27. Five out of the 37 affected patients achieved a score under 15, which suggests low self-esteem. The Rosenberg scale is not sensitive to identifying differences between individual groups. However, if we identify those subjects with low self-esteem and examine them further, we will find that the results of this subgroup differ from the results of other patients with all the questionnaires we used. The Mann-Whitney test found significant differences between the transformed (0-100) scores of the sociological questionnaire (U=8.00; Z=-3.153; p=0.002), the EQ-5D (U=10.50; Z=-3.189; p=0.001) and the self-completed DSI (U=11.00; Z=-2.996; p=0.003) and their subscales when we compared the results of the low (n=5) and the normal (n=32) self-esteem group. The low self-esteem group can be characterised by lower sociological satisfaction, worse subjective general health status and worse disease-specific quality of life. As a result, the low-esteem group specifically shows that self-esteem has an impact on subjective quality of life.

Method (3): Life quality from the perspective of sociology – results

According to the results of the self-compiled questionnaire, CTEV patients feel the most disadvantaged when planning a longer walk/ hiking, followed by achieving goals and ambitions. All 4 hard variables we used seem to affect the quality of life, and the Mann-Whitney test found significant differences in the following cases (n=37):

1. Regarding school- and work-related tasks, those over 18 are less hindered by their condition than underage subjects (U=111.5; Z=-1.977; p=0.048).
2. Regarding school- and work-related tasks, we found some difference between the genders (U=75.000; Z=-2.987; p=0.003), as females seem to be less affected than males.
3. As regards affectedness, we found significant differences in relation to hiking (U=107.5; Z=-1.958; p=0.05) and social relations (U=127.00; Z=-1.919; p=0.05), as unilateral CTEV turned out to be less of a hindrance.
4. As for the full score of the questionnaire (U=107.5; Z=-1.945; p=0.05) and 5 individual items (limited ability to exercise, inhibition to initiate intimate relationships, image of oneself and achieving ambitions) we found a significant difference between rural and urban residence, as those residing in a village were more hindered by their condition.

Internal consistency of the used instruments

The separate applicability of the individual questionnaires is indicated by the high values of internal consistency (Cronbach's Alpha value: proxy DSI: 0.87; satisfaction subscale: 0.85; function subscale: 0.74; self DSI: 0.92; EQ-5D-3L questionnaire: 0.83; Rosenberg Self-esteem Scale: 0.92, sociological satisfaction questionnaire: 0.93). Comparing the parental DSI with international sources provides similar values, which can be justified by data from Dietz (2009) (Cronbach's Alpha value: proxy DSI: 0.78; satisfaction subscale: 0.85; function subscale: 0.78). These results confirm the successful Hungarian adaptation of Roye's questionnaire.

Results of examining the correlation between the study tools

The combined application of the questionnaires was characterised by high (rs>0.6) Spearman correlation values. The strongest correlation was found between the DSI and the self-compiled sociological questionnaire (rs=0.916; p<0.001; n=37), which might be explained by fact that we specifically considered the problems of CTEV patients when compiling the questionnaire.

2. Examination of quantitative factors

When examining the quantitative factors, we presumed that the degree of lower leg atrophy would be related to function and that it would be an important feature of patients' quality of life.

In unilateral CTEV, the degree of lower leg atrophy is related to the other leg; however, in bilateral CTEV such a comparison is not feasible.

Method (4): Measuring lower leg length and circumference in the control group

Control group

We examined 543 subjects (308 males, 235 females, aged 4-22 years, mean age: 12.55 years) so that we could study the rate of the development of lower limb muscles.

Methods: we performed anthropometric measurements, focusing specifically on lower leg length and circumference.

Findings

Results of lower leg length measurements

According to our measurements, lower leg length is closely related to body height, and this relationship can be confirmed with linear, quadratic and cubic models as well ($p<0.001$). The best fit is provided by the quadratic model (R^2=). By using the quadratic regression model if you know the body height, you can calculate the estimated lower leg length. The following formula was used for the calculation:

$$\boxed{\text{lower leg length}=-22.502+52.018*\text{body height}-9.190*\text{body height}^2}$$

Results of lower leg circumference measurements

Lower leg circumference was closely related to body weight. In the case of lower leg circumference, all 3 regression models provided acceptable results at all levels of significance ($p<0.001$). The body weight-lower leg circumference scatter plot is best characterised by the cubic model; thus, the following formula can be used to calculate the estimated lower leg circumference:

$$\boxed{\text{lower leg circumference}=12.868+0.637*\text{body weight}-0.005*\text{body weight}^2+0.00002224*\text{body weight}^3}$$

For further calculations, if we know the body weight and height of patients with bilateral CTEV, we can calculate expected lower leg length and circumference and we can compare the actual and expected figures to obtain the difference.

Method (5): Measuring lower leg length and circumference in the study group

Study sample

While collecting data on lower leg length and circumference, altogether we examined 60 clubfeet in 60 patients (age: 3-30 years, mean age: 18 years, 62.5% males, 50% bilateral, traditional treatment).

Examination method

During the examination we took patients' history, performed physical examination and, if necessary, an x-ray was taken. We also measured body weight and height, lower leg length and lower leg circumference.

Findings

In unilateral clubfoot the mean difference between lower leg length was 0.86 cm ($p=0.01$, $n=20$, median=1.00, SD=0.83) and the mean difference between lower leg circumference was 3.13 cm ($p<0.001$, $n=20$, median=3.00, SD=1.57).

Our study found significant differences between the actual and expected lower leg length ($p=0.0019$, difference= -0,58) and lower leg circumference ($p<0.001$, difference= -4, in bilateral CTEV.

3. Comparison of qualitative and quantitative factors

Study group

The combined examination of qualitative and quantitative factors was performed in a group of 18 patients (mean age: 19.43 years, age:12-42 years, 10 unilateral and 8 bilateral CTEV, 10 males and 8 females).

Examination method

The Spearman correlation test was used to measure the strength of association between the individual items and overall findings of the DSI, EQ-5D-3L, Rosenberg scale and the sociological questionnaire and the differences in lower leg circumference.

Findings

In our sample of 18 patients, we did not find significant association between the questionnaires we used and the differences in lower leg circumference.

Hypotheses and evidence

1. The hypothesis that the general health condition of CTEV patients is worse than that of the general Hungarian population is rejected, as our study did not find any significant differences.
2. We accept the second hypothesis according to which it is worth supplementing the general health quality measurement tool with a specialised tool, as this latter instrument better characterises the health quality of CTEV patients, but the two tools are interrelated.
3. 'As for the quantitative factors, there is an objective measure that is characteristic of patient's health, thus serving as an important feature of CTEV patients' quality of life' – this hypothesis has to be rejected in view of the results of correlation between qualitative and quantitative factors.
4. 'The subjective self-assessment of CTEV patients is related to both the general and the disease-specific quality of life' – this hypothesis is accepted in view of the results of correlation between subgroups of different self-esteem.
5. 'As regards age groups, the self-assessment of adolescent patients shows greater variability' – this hypothesis is rejected, as variability did not differ significantly between the age groups.
6. We have to reject the hypothesis according to which patients with unilateral CTEV tend to have lower self-esteem than those with a bilateral deformity as the atrophy of the affected limb results in a clear difference between the two legs.
7. The sociological hypothesis of our study was fully supported. The performance of school and workplace tasks is affected by age and gender, affectedness influences free-time activities and social relationships, while residence has an impact on overall social satisfaction (disability, intimate relationships, acceptance, achieving ambitions).

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Novel findings of the research

- By analysing the answers that CTEV patients gave to the questions of EQ-5D-3L, we can compare the general health status of this group with that of those who have other chronic conditions and also with the health status of the Hungarian population.
- The results we obtained when examining the internal consistency and external validity of the DSI support the successful validation of the Hungarian version of the instrument.
- When using the Hungarian version of the DSI for the first time, we encountered some problems in analysing that arouse from the different coding of item 6. We had other difficulties with the same item due to its inverse relationship with all dimensions of the EQ-5D, and also with the limited number of answers that could be given for ‘pain’ (yes or no).
- By examining the self-esteem of CTEV patients with the Rosenberg scale and by identifying groups of different self-esteem (low and normal) we could show that low self-esteem does have an effect on the subjective quality of life.
- According to the findings of the sociological questionnaire, age, gender, affectedness and residence all have an impact on the quality of life. Rural residence has a negative effect on mobility, intimate relationships, social acceptance, achieving ambitions, as well as on overall sociological satisfaction.
- Based on the anthropological measurements of 543 subjects, we managed to determine two variables that are the most closely related to lower leg length and circumference: body height and body weight. If we have information on these two data, we can give an estimate of the expected lower leg length and circumference. Previously, the degree of developmental failure could only be determined in unilateral cases (difference between the circumference of the affected and the healthy leg) but based on our calculations it is now possible to determine the degree of developmental failure in bilateral CTEV as well.
- In unilateral CTEV we managed to determine the degree of difference between the length and circumference of the affected and the healthy lower leg.
- When examining the effect of objective and subjective factors on the life quality of 18 CTEV patients, we did not find significant correlation between the degree of lower leg circumference difference and any of the applied questionnaires.

Acknowledgements

I would like to express my special gratitude and thanks to my thesis supervisor, Prof. János Kránicz, M.D., whose outpatient clinics provided me with all the theoretical and practical assistance that set me on the road to the successful treatment of clubfoot. I am also deeply grateful to my co-supervisor, Henrietta Pusztafalvi Tigyi, M.D., whose assistance in choosing the appropriate methods and life quality assessment as well as writing my thesis has been invaluable.

I would like to express my appreciation to Dr. Kornélia Lovas for her generous help with choosing the life quality questionnaires and to Dr. Anikó Péter Kőnig, senior lecturer from the Institute of Bioanalysis, University of Pécs (PTE) for her guidance on statistical analysis.

I am also indebted to Dr. András Sramó and Dr. Károly Berényi for their assistance in statistical calculations.

I am thankful to Vanda Varga for her help with the compilation of the Hungarian version of the DSI.

I would like to express my heartfelt thanks to Dr. Szilvia Jámbori Bárány, senior lecturer and psychologist, for her advice and suggestions in connection with the psychological examination.

I got an insight into the sociological background from Dr. István Marczin, associate professor and sociologist from the Faculty of Cultural Sciences, Education and Regional Development, PTE, and I am deeply grateful for that.

I would also like to thank all my former and current colleagues at the Institute of Physiotherapy and Sport Science (PTE), Department of Orthopaedics (PTE) and Eötvös József College for their encouragement and support.

I am also thankful to the respondents of my questionnaires, who gave their precious time to help me accomplish this project.

Naturally, this acknowledgement would not be complete without thanking my husband and sons, who supported me throughout my entire study. Without their patience, loving support and encouragement I would not have been able to complete this thesis.

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