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Application of T₁ scale in evaluating effects of long-term therapy



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ABSTRACT

Introduction: Modern medicine employs various approaches to analyzing data collected through clinical observation. The results of such analyses demonstrate general tendencies of the observations, yet they do not point to the dynamics of the therapeutic process.

Aim: The authors of the present study propose introducing the T_1 scale, thanks to which one can analyse the results and course of each patient's treatment in relation to normal distribution. The aim of this study is to prove that T_1 scale is functional in evaluating the effects of long-term therapy.

Material and methods: The study shows that T_1 scale, which is realized through the formula $y = 10z_i + 50$, is a universal scale. It has been concluded that the interval of T_1 scale determines effective dynamics of therapeutic procedures. The study encompasses 234 term infants born with normal weights who were diagnosed with neurodevelopmental disorders. The subjects were observed every 6 weeks. T_1 scale was applied in order to evaluate the dynamics of clinical change of the analysed features.

Results and discussion: The scale precisely differentiates the population, that is the number of patients for whom beneficial therapeutic effects were observed, the closer the values in T_1 scale are to the mean value of T_1 scale. T_1 scale makes it possible to evaluate clinical observations in the treatment process in a precise manner in line with evidence-based medicine (EBM).

Conclusions: T_1 scale makes it possible to evaluate clinical observations in the course of treatment in a precise manner in line with EBM.

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1. Introduction

All the dynamically developing branches of modern science, including medicine, should evaluate incidents and observations. In order to ensure that, one needs to apply mathematical models as well as statistical analysis, which can be predicted during the research planning.¹

According to the authors, all the investigations are to focus on determining the effects of therapeutic procedures. At present, medical viability is determined by conclusions drawn on the basis of studies performed in line with evidence-based medicine (EBM).²

Following these rules, one needs to carefully select methods of analysis of the observations. The obtained results can have various clinical values, which can in turn be decisive in choosing a particular treatment.³

The authors believe that T_1 scale presents differences in the clinical value of research conclusions in line with the rules of EBM. The study constitutes an attempt to apply the solutions of a mathematical model of T_1 scale in which standard deviation is a unit of measurement in order to interpret clinical results.⁴ This is especially crucial because a human being is a subject of therapeutic procedures, it is a particular patient, and the time of commencing the treatment, its length and dynamics play a decisive role when it comes to therapeutic success.^{5–7}

The name of T_1 scale as a mathematical model is validated by the fact that the correlations between a priori and a posteriori results constitute simplified assumptions. Currently in medicine various approaches to clinical data analysis are followed, most often researchers apply an analysis of results variability with Student's t- or χ^2 -distribution, or a correlation of variables with Pearson correlation coefficient, linear regression, etc. These methods do not demonstrate the dynamics of a therapeutic process.

2. Aim

To show the functional application of T_1 scale in evaluating the dynamics of long-term therapy.

3. Material and methods

The study encompassed 234 term infants with normal weights diagnosed with neurodevelopmental disorder during a routine pediatric examination. The patients were referred with a diagnosed posture asymmetry. Identifying the disorders constituted the basis for extended examination of psychomotor function and for implementing treatment in the Rehabilitation Department of Children's Hospital in Kielce. Following the neurokinesiological assessment, central coordination disorder related to the posture asymmetry was found, which according to Vojta is a basis to implement treatment.⁸ The examination included assessing the whole range of psychomotor functions of the infants according to the model proposed by the Children's Centre in Munich.⁹ This model assesses neurodevelopmental changes and the level of

functional ability on the basis of four criteria: (1) the level of social interaction; (2) spontaneous motor function in the supine position and the lying face down position; (3) seven postural responses according to Vojta; and (4) neurological reflexes according to Vojta.¹⁰ Each of the analysed features was assigned 0 (for pathological responses), 1 (for partly abnormal responses), or 2 (for normal responses). Next, values in T_1 scale were attributed to these scores. The observations were performed every 6 weeks. All the children were undergoing rehabilitation treatment program with the use of Vojta's method, SI and NDT-Bobath techniques until optimal improvement of their motor function was achieved. The observations were performed in 2009–2012 in Kielce Province Children's Hospital.

3.1. Statistical analysis

In order to establish a method to evaluate the dynamics in longterm therapy, normal distribution was applied.¹¹ The density function of normal distribution is determined as follows:

$$f(z) = \frac{1}{\sqrt{2\pi}} e^{-\frac{1}{2}z^2}$$
(1)

where standardized score (z) is defined as:

$$z = \frac{x_i - x_m}{\sigma}$$
(2)

while

 x_i – ith empirical score, x_m – the mean score, σ – the standard deviation.

The parameters of normal distribution, that is the expected value (x_m) and standard deviation (σ) were calculated according to the following formulas^{12,13}:

$$\mathbf{x}_m = \frac{1}{n} \sum_{i=1}^n \mathbf{x}_i \tag{3}$$

$$\sigma = \sqrt{\frac{\sum_{i=1}^{n} (x_i - x_m)^2}{n}}$$
(4)

where n – the number of scores.

Standardized scores are difficult to interpret due to the fact that they may assume negative, positive and zero value. Thus a new scale was construed, in which scores become positive and equivalent to empirical results. The equivalence is ensured by the relationship of equality between the empirical standardized scores and the standardized scores in the new scale.¹⁴

The standardized score z_y in the new scale was defined as:

$$z_y = \frac{y - b}{a} \tag{5}$$

where

- y the score in the new scale a priori,
- b the mean value of scores in the new scale a priori,
- *a* the standard deviation in the new scale a priori.

The relationship of equality of standardized scores, that is the standardized scores (formula 5) which result from the scale

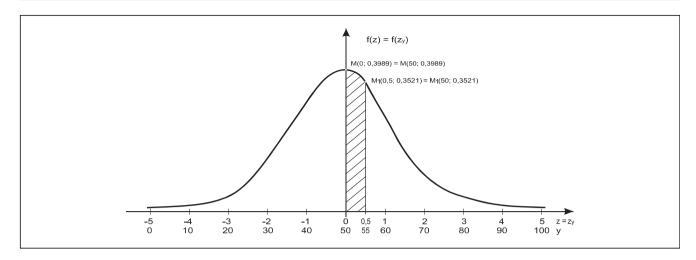


Fig. 1 – Graphic illustration of function f(y) = f(z) in T₁ scale.

a priori, and the empirical standardized scores – a posteriori (formula 2), allows one to express the empirical scores in the new scale as follows:

$$\frac{y-b}{a} = \frac{x_i - x_m}{\sigma} \tag{6}$$

After transformation:

$$y = a \frac{x_i - x_{sr}}{\sigma} + b \tag{7}$$

Thus:

$$y = az_i + b \tag{8}$$

Formula 7 is T scale. When it is assumed that: a = 10; b = 50, formula 7 is T₁ scale, in the form of

$$y = 10z + 50$$
 (9)

The normal distribution density functions for the standardized scores and for the scores in T scale have the same values since on the basis of formula 1 we arrived at^{15} :

$$f(z_{y}) = \frac{1}{\sqrt{2\pi}} e^{-\frac{1}{2}\left(\frac{y-b}{a}\right)^{2}} = \frac{1}{\sqrt{2\pi}} e^{-\frac{1}{2}\left(\frac{az+b-b}{a}\right)^{2}} = \frac{1}{\sqrt{2\pi}} e^{-\frac{1}{2}z^{2}} = f(z)$$
(10)

The above formula is illustrated in Fig. 1.

The values on the axis of abscissa are the standardized scores from -5 to 5 (Fig. 1). These scores are equivalent to the values expressed in T_1 scale as a result of formula 9 and amount respectively to

$$\begin{array}{l} 0 \leftrightarrow 10 \cdot 0 + 50 = 50; \\ 1 \leftrightarrow 10 \cdot 1 + 50 = 60; \\ 2 \leftrightarrow 10 \cdot 2 + 50 = 70; \\ -1 \leftrightarrow 10 \cdot -1 + 50 = 40; \\ -2 \leftrightarrow 10 \cdot -2 + 50 = 30 \ \text{etc.} \end{array}$$

Formula 10 shows that $f(z_y) = f(z)$. It means that the values of the standardized scores are equal to the standardized scores in T scale, and consequently in T₁ scale. These values can be

calculated on the basis of formula 1, and for instance for the standardized score 0:

$$f(0) = \frac{1}{\sqrt{2\pi}} e^{-\frac{1}{2}0^2} = \frac{1}{\sqrt{2\pi}} e^0 = 0.3989 \tag{11}$$

This is the highest value which was marked in Fig. 1. The remaining values $f(z_y) = f(z)$ were collected in a chart in line with formula 1. Table 1 shows some values, starting from the highest, that is the standardized score 0 and value 0.3989. In the last column T₁ scale scores are presented. On the axis of ordinates scores were calculated according to formula 1.

The goal of every therapeutic procedure consists in helping as many patients as possible to achieve a good health condition. That is why standardized scores were taken into consideration, on the axis of abscissa $z \ge 0.16.17$

As the standardized score +1 deviates from the mean standardized score, i.e. zero (0), by +1 and -1, referring all the scores to the critical value at the level of confidence coefficient $\alpha = 0.05$, which is: $t_{0.05,\infty} = 1.96$ (the value read from the charts of Student's t-distribution), what follows was found:

$$\begin{split} z_+ &= \frac{1}{1.96} \approx 0.5, \\ z_- &= \frac{-1}{1.96} \approx -0.5. \end{split}$$

Table 1 – Values for $f(z_y) = f(z)$.				
Standardized score	Value of function f(z _y) = f(z)	Scores in T ₁ scale		
0	0.3989	50.0		
0.05	0.3984	50.5		
0.10	0.3970	51.0		
0.15	0.3945	51.5		
0.20	0.3910	52.0		
0.25	0.3867	52.5		
0.30	0.3814	53.0		
0.35	0.3752	53.5		
0.40	0.3683	54.0		
0.45	0.3605	54.5		
0.50	0.3521	55.0		

These values in T_1 scale in line with formula 9 are respectively:

$$\begin{array}{l} y_+ = 10 \cdot 0.5 + 50 = 55 \\ y_- = 10 \cdot -0.5 + 50 = 45 \end{array}$$

Thus we arrived at the interval for positive and negative scores (45–55). The interval for positive scores is (50–55), and for negative scores (45–50).

The study employs the interval for positive scores referring them to normal distribution. The closer the score in T₁ scale to 50, the better the result of therapy. At the level of confidence coefficient $\alpha = 0.05$, with $t_{0.05,\infty} = 1.96$, the results of treatment were differentiated, analogously to the previous pattern.

Thus:

$$\begin{split} z_{0.1} &= \frac{0.1}{1.96} \approx 0.05 \\ z_{0.3} &= \frac{0.3}{1.96} \approx 0.15 \\ z_{0.5} &= \frac{0.5}{1.96} \approx 0.25 \end{split}$$

The values in T_1 scale are respectively:

 $y_{0.1} = 10 \cdot 0.05 + 50 = 50.5$ $y_{0.3} = 10 \cdot 0.15 + 50 = 51.5$

$$v_{0.5} = 10 \cdot 0.25 + 50 = 52.5$$

Thus differentiated intervals for positive scores were interpreted as follows: 50.0–50.5 as very certain scores; 50.5–51.5 as certain scores; 51.5–52.5 as average certain scores; 52.5–55.0 as correct scores.

In order to show the dynamics of long-term therapy the best result of every patient (one to which 2 was attributed) was evaluated. The results of clinical observations of every component of the study in T₁ scale in line with formula 9, y = 10z + 50, are shown in Table 2. The score of the first observation performed to evaluate social interaction (and analogously all the remaining scores in patients in each of the four kinds of tests) was arrived at as follows: the mean score of the population is $x_m = 0.498$ (formula 2), the standard deviation $\sigma = 0.7793$ (formula 4), and on the basis of formula 9 $y = 10\frac{2-0.498}{0.7793} + 50 = 69.27$ – observation 1 performed to evaluate social interaction (Table 2).

4. Results

The scores in Table 2 provide the following information:

1. In observation 1 for all the samples the score was beyond the 50.0–55.0 interval.

- 2. The worst scores of observation 1, that is in the moment when treatment was implemented, were found in children with central coordination disorders in the evaluation of spontaneous motor function (88.15) and in the evaluation of postural responses according to Vojta (88.01).
- 3. The pace of changes in the scores in T₁ scale for children with central coordination disorders differed for each of the assessed type of observations.
- 4. The expected interval 50.0–55.0 was achieved by the patients in the fourth observation the soonest when it comes to the evaluation of neurological responses (54.01) and in the evaluation of social interaction (54.12).

On the basis of the aforementioned criteria, the best result of the examination of neurological responses was determined as averagely certain, while the best result of the examination of spontaneous motor function, postural responses according to Vojta and social interaction as correct.

5. Discussion

The fact that there were no statistical methods that would allow the authors to analyse the dynamics of the therapeutic process encouraged them to propose T1 scale.18-21 Metaanalysis are often applied in articles in order to verify effectiveness of therapy, which do not refer to therapeutical decisions on particular investigation level.²² So far, in order to measure the effects of long-term therapy various studies applied χ^2 test, Student's t-distribution and even Spearman correlation coefficient of Mann-Whitney test.¹⁹⁻²² Null hypothesis (H₀) was verified between the initial and final results.²³ This is a simplified method to analyse the results since it does not account for the dynamics of the therapeutic process. Effectiveness of the above mentioned statistical methods depends on various factors indicated at the beginning of a research.^{24–26} This lack have been eliminated in the proposed T₁ scale. It allows researchers to investigate the therapeutic process of each patient. Thus, providing the analysis of clinical results, one can express empirical results through standardized results in T scale, and consequently T_1 scale, which are positive scores that facilitate interpreting changes that occur in the therapeutic process. Thus, when the treatment is divided into stages it is possible to analyse the dynamics of therapeutic effects in groups of patients and determine levels of effectiveness as: very certain, certain, satisfactory, and correct in the 50.0–55.0 interval. Thanks to T₁ scale it is possible to observe when and at which pace general criteria are met, that is when patients' results reached the

Table 2 – The dynamics of therapeutic effects in children with central coordination disorders.					
Observation	Level of social interaction	Spontaneous motor function	Postural responses according to Vojta	Neurological responses	
1	69.27	88.15	88.01	67.08	
2	62.33	70.97	67.92	61.11	
3	59.11	61.12	63.31	56.47	
4	54.12	56.07	56.42	54.01	
5	52.77	54.03	53.55	52.21	

50.0-55.0 interval, and when the evaluated children reached their optimal level of ability. The authors based their research on the study by Guilford,⁴ which shows evaluating empirical results in T scale through the result of accumulated proportions referred to normal distribution. As a consequence, Guilford eliminated negative standardized scores which were difficult to interpret. It is an advantage of T_1 scale that it differentiates the population, which is confirmed in the following statements: (1) the 'less often' the positive score of clinical observations occurs in empirical studies, the higher the score in T_1 scale and the farther it is from the 50.0–55.0 interval, and (2) the 'more often' the positive score of clinical observations occurs in empirical studies, the lower the score in T_1 scale and the closer it is to the 50.0–55.0 interval. It has been established that if both conditions (1) and (2) are met, the population of children with central coordination disorders is differentiated in various degrees. T1 scale was applied to show the dynamics of effects which occurred in the therapeutic process. This scale precisely differentiates the population, that is the higher the number of patients who show positive treatment effects in subsequent observations, the closer to the 50.0–55.0 interval the scores in T₁ scale. T₁ scale was applied in the present study to evaluate the dynamics of therapeutic process in children with central coordination disorders.²⁷

 T_1 scale meets the definition of a model as a collection of simplifying assumptions which are related in a certain way. T_1 scale is a mathematical model in line with the EBM requirements for evaluation of effects of long-term therapy.

6. Conclusions

- 1. The same values are attributed to the standardized scores and the scores in T_1 scale.
- T₁ scale makes it possible to assess the effectiveness of treatment procedures.
- 3. T₁ scale makes it possible to evaluate clinical observations in the course of treatment in a precise manner in line with EBM.

Conflict of interest

None declared.

REFERENCES

- 1. Nietert PJ, Dooley MJ. The power of the sign test given uncertainty in the proportion of tied observations. *Contemp* Clin Trials. 2011;32(1):147–150.
- Colemana DA, Yub R. The other randomization methods for labeling drug kits. Contemp Clin Trials. 2014;38(2):270–274.
- 3. Djulbegovic B, Kumar A, Kaufman RM, Tobian A, Guyatt GH. Quality of evidence is a key determinant for making a strong GRADE guidelines recommendation. J Clin Epidemiol. 2015;68 (7):727–732.
- 4. Guilford JP, Fruchter B. Fundamental statistics in psychology and education. New York, London: McGraw-Hill Company; 1977.

- Giżewski T, Wac-Włodarczyk A, Goleman R, Kowalski IM. Neural classifier of similarity groups applied in selected virtual image of defects. Przeg Elektrotech. 2011;87(12b):53–56 [in Polish].
- Buciński A, Kowalski IM, Zarzycki D, Bączek T, Nasal A, Kaliszan R. Principal component analysis of patient variables as an objective method of treatment evaluation in adolescent idiopathic scoliosis. *Adv Clin Exp Med*. 2002;11 (1):61–68.
- Buciński A, Bączek T, Kowalski IM. Clinical data analysis with the use of artificial neural networks of treatment evaluation in adolescent idiopathic scoliosis. Adv Clin Exp Med. 2004;13(4):623–629.
- Müller H, Vojta V. Early diagnosis and therapy of cerebral disturbances of motility in infancy. Z Orthop Ihre Grenzgeb. 1974;112(2):361–365 [in German].
- 9. Vojta V. Cerebral movement disturbances in infancy. Early diagnosis and early treatment. Stuttgart, New York: Georg Thieme Verlag; 2008 [in German].
- Vojta V. Early management of children with cerebral palsy hazards. Analysis of final results. Monatsschr Kinderheilkd. 1973;121(7):271–273 [in German].
- Limpert E, Stahel W, Abbt M. Log-normal distributions across the sciences: keys and cluesbioscience. BioScience. 2001;51(5):341–352.
- Wright HC, Sugden DA. A two-step procedure for the identification of children with developmental co-ordination disorder in Singapore. *Dev Med Child Neurol.* 1996;38(12): 1099–1105.
- Golberger AS. The interpretation and estimation of Cobb-Douglas functions. Econometrica. 1968;35(3–4):464–472.
- 14. Freeman J, Modarres R. Inverse Box–Cox: the power-normal distribution. Stat Probab Lett. 2006;76(8):764–772.
- Box G, Cox D. An analysis of transformations. J R Stat Soc B. 1964;26(2):211–252.
- Teekens R, Koerts J. Some statistical implications of the log transformations of multiplicative models. *Econometrica*. 1972;40(5):793–819.
- Cohen J. Statistical power analysis for the behavioral sciences. New York: Acadmic Press; 1977.
- Atkins D, Best D, Briss PA. GRADE Working Group: grading quality of evidence and strength of recommendations. BMJ. 2004;328:1490. http://dx.doi.org/10.1136/bmj.328.7454.1490.
- Guyatt GH, Oxman AD, Schünemann HJ, Tugwell P, Knottnerus A. GRADE guidelines: a new series of articles in the Journal of Clinical Epidemiology. J Clin Epidemiol. 2011;64(4):380–382.
- 20. Straus SE, Shepperd S. Challenges in guideline methodology. J Clin Epidemiol. 2011;64(4):347–348.
- Duggal R, Menkes DB. Evidence-based medicine in practice. Int J Clin Pract. 2011;65(6):639–644.
- Novianti PW, Roes KC, Ingeborg T. Estimation of betweentrial variance in sequential meta-analyses: a simulation study. Contemp Clin Trials. 2014;37(1):129–138.
- Sheskin DJ. Handbook of parametric and nonparametric statistical procedures. 4th ed. Boca Raton, FL: Chapman & Hall/ CRC; 2007.
- Shoukria MM, Donnerb B, El-Dalid A. Covariate-adjusted confidence interval for the intraclass correlation coefficient. *Contemp Clin Trials*. 2013;36(1):1244–1253.
- Kowalski IM, Kotwicki T, Siwik P. Analysis of diagnostic methods in trunk deformities in the developmental age. Pol Ann Med. 2013;20(1):43–50.
- 26. Giżewski T, Kowalski IM, Zarzycki D, Radomska-Wilczewska A, Lewandowski R, Kotwicki T. Model of self-learning system in medical diagnostics. Pol Ann Med. 2008;15(1):34–42.
- 27. Bland JM, Altman DG. Statistical methods for assessing agreement between two methods of clinical measurement. *Lancet.* 1986;1(8476):307–310.