

## Development of a screening tool for children's growing pains: validation, reliability control and clinical evaluation

Maria Vasilopoulou<sup>1</sup>, Anastasios Spathis<sup>2</sup>, Nikos Myriokefalitakis<sup>3</sup>, Foteni Zaferopoulou<sup>1</sup>, Ioanna Paspati<sup>2</sup>, Maria Tsolia<sup>4</sup>

<sup>1</sup> Pediatric Intensive Care Unit and <sup>2</sup> Orthopedic Clinic, Penteli Children's Hospital, Penteli, <sup>3</sup> Hellenic Pediatric Society, <sup>4</sup> 2<sup>nd</sup> Department of Pediatrics, School of Medicine, National and Kapodistrian University of Athens, "P. and A. Kyriakou" Children's Hospital, Athens, Greece. E-mail: mariza.vass@gmail.com

Received: 14 May 2015, Revised: 17 November 2015, Accepted: 2 March 2016

**SUMMARY:** Vasilopoulou M, Spathis A, Myriokefalitakis N, Zaferopoulou F, Paspati I, Tsolia M. Development of a screening tool for children's growing pains: Validation, reliability control and clinical evaluation. Turk J Pediatr 2015; 57: 467-474.

Growing pains (GP) is the most common musculoskeletal complaint in childhood. The present study describes the development, validation and clinical evaluation of a questionnaire for the detection of GP in the general children's population aged 4 -7 years of age.

Based on the existing publications, a 27-point closed type questionnaire was developed and was administered to a parental population of school-age children for standardization. Nine questions evaluating pain localization, intensity and 24-hour temporal distribution, exhibited excellent validity and reliability and were finally selected. A cut-off point of  $\geq 8$  was proposed for GP's diagnosis.

Questionnaire's sensitivity and specificity were studied in a sample of outpatient children attending an orthopedic clinic for lower limb pain of no apparent traumatic origin. The diagnosis of GP based on the questionnaire coincided with the orthopedic diagnosis in all cases. The proposed questionnaire is a reliable and valid screening tool for GP.

*Key words:* children, growing pains, leg pains, questionnaire, diagnosis, specificity, sensitivity.

Recurrent lower limb pain is the most common musculoskeletal complaint in childhood<sup>1,2</sup> and is a common cause of referral to pediatricians.

It is referred as "growing pains" (GP) and represents a non-inflammatory pain syndrome of obscure etiology, that affects children aged 4- 14 years of age, with a peak frequency between 4 and 6 years<sup>3</sup>.

Growing pains present with certain characteristics that help distinguish them from other clinical entities. These characteristics were best described by Peterson<sup>2</sup>: the pain is intermittent and bilateral, it is localized in the lower extremities (muscular bulks of the thigh and calf), it is not articular, it occurs typically at night with full resolution by morning, it

does not affect the child's normal activity and there are no systemic signs or symptoms of disease. Physical examination and laboratory tests are normal.<sup>2,4</sup>

Despite its interest as a clinical entity, there are two major issues that remain unclear. At first, the prevalence of growing pains among children varies considerably in different studies, ranging from 2.6 % to 49.4%, depending upon the population studied, the age of the children and the clinical definition used<sup>4</sup>; knowledge of the specific prevalence is needed in order to study this clinical entity<sup>5</sup>. The second issue refers to the lack of a definite epidemiological protocol for the diagnosis of growing pains in children who complain of leg pain or a screening questionnaire for the general population. The

most current study on the issue is that of Evans and Scutter<sup>6</sup>, who based on Peterson’s definition for growing pains<sup>2</sup>, have developed a questionnaire with good validity and reliability, addressed to parents of preschool children with suspected growing pains. However, there is no weighted self-report questionnaire for parents neither internationally, nor nationally.

The aim of this study was the development of a questionnaire suitable for screening of growing pains among children aged 4-7 years of age in the general population. Furthermore, to create a reference scale with a cut-off value above which a high index of suspicion for growing pains would exist. Such a scale should be suitable to use in the community as well as in the doctor’s office.

This was a preliminary study; the described questionnaire is now being used to evaluate the prevalence of growing pains in Greek schoolchildren. Final data are expected in the near future.

The study was conducted in two phases:

Phase 1. Assessment of questionnaire’s validity and reliability Phase 2. Assessment of questionnaire’s sensitivity and specificity.

**Assessment of Questionnaire’s Validity And Reliability**

**Material and Methods**

*Development of the “Questionnaire for the detection of growing pains” (see Appendix)*

Initially a 30- item questionnaire referring to GP was developed. GP localization, duration, 24 hour temporal distribution and relation to other conditions were addressed. Questionnaire’s content validity was based on the review of the international literature, the review of the questions by specialists in the field and the reforming of the questions after a pilot study.

A pilot study was conducted on a sample of parents of school children (n=20) that attended a randomly selected elementary school in the region of Attica. The parents were asked to fill out the questionnaire in the presence of the researchers, so that the time needed, the clarity of the questions and the need for changes could be assessed. Based on the pilot study results, the initial form was amended and the final questionnaire consisted of 27

descriptive, easily comprehended, closed-type questions. Estimated answering time was less than 10 minutes.

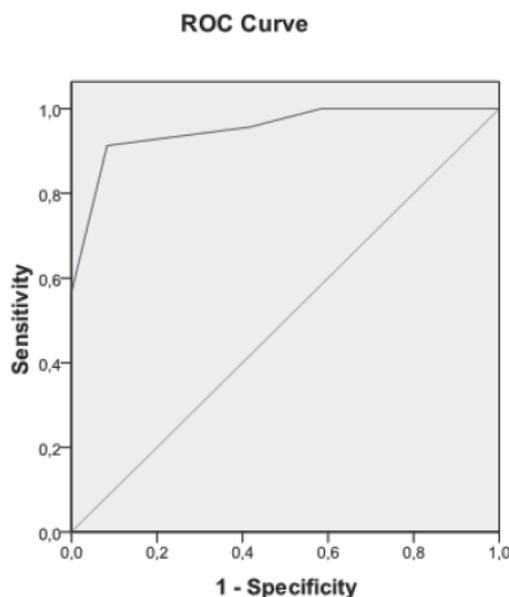
The 27- version is included as an appendix.

**Sample**

The study was conducted among children aged 4-7 years of age, pupils of a private elementary school in the region of Attica<sup>7</sup>. The school was selected randomly.

The questionnaire was administered to parents of 95 children attending kindergarten and first grade in the selected school. Inclusion criteria were: 1) age of patients between 4 and 7 years, 2) knowledge of the Greek language.

Exclusion criteria were: 1) age of patients



**Coordinates of the curve**

Positive if Greater Than or Equal To	Sensitivity	1 - Specificity
-1,0000	1,000	1,000
1,5000	1,000	,917
3,5000	1,000	,833
4,5000	1,000	,583
5,5000	,957	,417
6,5000	,913	,083
7,5000	,565	,000
8,5000	,174	,000
10,0000	,000	,000

Fig 1. Area Under the Curve (AUC) was equal to 0.953. The theoretical excellent sensitivity/specificity point was set at 6.5.

**Table I.** Score on the Proposed Screening Scale for Growing Pains

Score	N	%	Total %
1.00	1	1.2	1.2
2.00	3	3.6	4.8
3.00	6	7.2	12.0
4.00	6	7.2	19.3
5.00	16	19.3	38.6
6.00	12	14.5	53.0
7.00	19	22.9	75.9
8.00	18	21.7	97.6
9.00	2	2.4	100.0
Total	83	100.0	

**Comment:**

On the proposed screening scale for growing pains, 21.7% of children scored 8 whereas 2.4% of children scored 9. Thus 21.7% + 2.4% = 24.1% of the sample scored ≥ 8, which is compatible with the diagnosis of growing pains. Also this result is compatible with the estimated prevalence of growing pains according to the literature. Consequently, we assume that in order to have a more definite diagnosis of growing pains, one should have at least 8 answers compatible with the diagnosis.

younger than 4 years and older than 7 years, 2) questionnaires partially completed by the parents.

**Statistical analysis**

G power 3.1.3 was used to calculate statistical power: [sample size =77, when  $\alpha$  err prob =0.05 and power (1- $\beta$ ) =0.90].The data were analyzed on the SPSS 22.0 program. First, the main parameters were analyzed and the indices of internal validity of the scales were calculated. In order to assess the *structure validity* of the questionnaire and to determine the evaluation parameters for growing pains, there was a *factor analysis*. The suitability of the data for factor analysis was studied through the sampling capability of Kaiser –Meyer- Olkin (KMO) =0.61. As a measure for the choice of parameters' number the values >1 were used (Kaiser measure). The threshold to include a question into the scale was a burden value ≥0.40. Also, additional analysis of the main parameters was done and it confirmed the allocation of each question in nine sectors.

Then the questions reliability was determined. Low reliability questions were those that had Cronbach validity coefficient  $\alpha < 0.60$  or test-retest coefficient  $r < 0.5$ . The validity of re-testing was assessed through the Kappa score

(degree of coherence for categorical variables).

**Results**

Eighty-three parents of 44 boys and 39 girls provided informed consent and agreed to fill it out (response rate 87.3%).

**Structure Validity**

Following a validity assessment, questions with a burden value < 0.40 were excluded. Twenty-one questions were incorporated in nine factors with a Cronbach validity coefficient  $\alpha=0.68$  for the sum of the questions. These nine factors account for the 87.3% of the initial variation. The internal validity index of the scale was Cronbach's  $\alpha= 0.68$ . In detail, the dimensions of the exploratory factor analysis were as follows:

Clinical and laboratory assessment: questions 24,25,26 -  $\alpha=0.72$ ,

Pain severity : questions 8,9,11,12 -  $\alpha= 0.82$ ,

Unilateral pain: questions 6,7 -  $\alpha= 0.73$ ,

Pain localized inside muscle bulks of the lower extremities or behind the knees: question 1,

Temporal distribution: questions 3,4,5,13 -  $\alpha= 0.62$ ,

General condition : question 10,

Accompanying conditions: questions 15,17,18,19 -  $\alpha= 0.70$ ,

Accompanying findings : question 2

Heredity : 27

**Reliability**

Three weeks later, the parents were asked to answer to the questions again so that the reliability of re-testing could be assessed. All 83 forms were returned.

The mean reliability of re-testing was 75.4% (0.33-100% [ $p<0.001$ ]) and the Cronbach coefficient varied among 0.62-0.82 for the subscales. The lowest reliability was observed for questions 2 ,3,8 and 24-27 (degree of coherence 30-40%) .

The test-retest reliability was 0.76 and its internal consistency coefficient was equal to  $\alpha=0.68^{6,7}$

**Proposed diagnostic scale**

After exclusion of low reliability questions,

**Table II.** Questions of the Proposed Diagnostic Scale for Growing Pains

Number	Questions (the numbers correspond to the initial questionnaire)
1	Location of the pain: Muscles (thighs, gluteal, calves, soles). Behind the knees.
2	4. The pain occurs during late afternoon or night.
3	5. The pain is still present next morning.
4	6. The pain is bilateral.
5	7. The pain affects always the same leg.
6	9. The child awakes at night because of pain.
7	10. The child is otherwise well.
8	11. The pain resolves spontaneously or with massage of the affected area.
9	13. The pain is persistent and doesn't resolve.

a scale of diagnostic criteria for growing pains was developed that included questions 1,4,5,6,7,9,10,11,13 ( nine questions in total). The scale had a Cronbach  $\alpha=0.73$ . The answer to each question was given a value (0 or 1) according to its relation to the diagnosis (0=not related, 1=related). Affirmative answer to the questions 1,4,6,9,10,11 was compatible with the diagnosis, as well as negative answer to the questions 5,7,13. The maximum score was 9 (totally compatible score with the diagnosis) and the lowest was 0 (not compatible with the diagnosis). On the proposed screening scale for growing pains 24.1% of the sample scored  $\geq 8$ , which is compatible with the diagnosis of growing pains (Table I). Also this result is compatible with the estimated prevalence of growing pains according to the literature. Consequently, a score  $\geq 8$  creates a high index of suspicion for growing pains as the explanation for the child's complaints. The questions of the proposed scale are shown on Table II.

#### Assessment of Sensitivity and Specificity

Since the *gold standard* for the diagnosis of growing pains is the orthopedic evaluation, a clinical study was conducted in order to investigate the sensitivity and specificity of the aforementioned proposed diagnostic scale<sup>8</sup>.

#### Material and Methods

##### Instrument

The nine-point diagnostic scale (Table II). A cut-off value  $\geq 8$  was considered diagnostic of growing pains.

##### Method

The questionnaires were administered to parents of consecutive children who visited the outpatient orthopedic clinic complaining of lower limb pains of no apparent traumatic origin. All children were of Greek origin. Parental informed consent and approval by the hospital ethics committee were provided.

Inclusion criteria were: 1) age of patients between 4 and 8 years, 2) orthopedic evaluation requested by the family because of lower limb pain, 3) completion of the questionnaire by the

**Table III.** Questionnaire and Orthopedic's Diagnosis Cross Tabulation (scoring cut-off point  $\geq 8$  )

		Questionnaire's Diagnosis		Total
		Negative for GP	Positive for GP	
Orthopedic's diagnosis	Negative for GP	12	0	12
	Positive for GP	10	13	23
Total		22	13	35

When the cut-off point was set  $\geq 8$ , specificity was 100% and sensitivity was 56.5%.  
GP: Growing pains

parents while awaiting for clinical examination, 4) orthopedic report available for review and 5) knowledge of the Greek language.

Exclusion criteria were: 1) age of patients younger than 4 years and older than 8 years, 2) lower limb pain of any reported traumatic cause.

All evaluations were performed by two physicians at the outpatient orthopedic department. The physicians were blind to parents' answers to the questionnaire and to the score each patient achieved. They could also order laboratory investigations (X-rays, blood test) whenever they considered it necessary. Finally, a researcher collected the completed questionnaires, estimated the score for each patient and reviewed the orthopedics' clinical report. Duration of the study was one year, from January 1<sup>st</sup> 2013 until December 31<sup>st</sup>.

### Statistical analysis

All data were entered into a SPSS 17.0 data sheet. Descriptive statistics and ROC analysis were performed.

### Results

The questionnaires were filled out by 35 parents of 35 consecutive children (16 males). Mean age of children participating in the study was  $6.85 \pm 1.61$  years. According to the orthopedic evaluation 23 children were classified as having growing pains, 7 were diagnosed with overuse syndrome, 2 with hip joint transient synovitis, 2 with calcaneal apophysitis and 1 with spondylolisthesis. Regarding questionnaire scoring, 13 patients scored above 8, 14 between 6 and 7 and 8 children scored below 6. Taking the orthopedic diagnosis as reference, there were 13 true positive (TP) results, 12 true negative (TN), no false positive (FP) and 10 false negative (FN). As sensitivity is defined  $TP/TP+FN$  and specificity  $TN/TN+FP$ , when the cut-off point is set at  $\geq 8$ , the calculations result in 56.5% sensitivity and 100% specificity (Table III). However, when the cut-off point is set at  $\geq 7$ , the calculations are as follows: sensitivity  $(21/21+2) = 91.3\%$  and specificity  $(21/21+1)=95.4\%$ .

Regarding ROC analysis, Area Under the Curve (AUC) was equal to 0.953 (Fig. 1). The theoretical excellent sensitivity/specificity point

was set at 6.5.

### Discussion

The aim of the first part of the study was the development of a valid and reliable questionnaire for screening of growing pains in the general population. The proposed questionnaire has satisfactory overall internal validity and reliability. Part of the questions that referred to conditions that worsen the pain, were not valid enough and were excluded from the final form. It is of note that those questions addressing the duration of the pain (regardless of the timing during the day), the physical findings on the site of the pain, the relation of the pain to the weather, the heredity and the pediatrician's opinion showed the lowest reliability and were also excluded from the proposed scale. The low reliability of these questions could be attributed either to their general nature or the time to re-testing. It is possible that during the time between the first and second time of filling out the questionnaire, the parents discussed the matter and changed their original opinion. During the pilot study, there was fruitful discussion with the parents that helped to reform the questions and to give advice and clarify details to them. However, there was no follow-up of the children so that the diagnosis of growing pains could be confirmed and thus the sensitivity and specificity would be assessed.

The second part of the study attempted to explore the sensitivity and specificity of the proposed nine-point questionnaire for the detection of growing pains in children. According to this questionnaire, the cut-off value in order to consider the diagnosis of growing pains as valid is very high (8 out of 9). The results of the study showed a high specificity, when the proposed cut-off value was used, but low sensitivity. When *lowering* the proposed screening *cut-off value* (i.e 7 points instead of 8), sensitivity and specificity in the study sample were excellent. However, the zone between 6-8 points is considered crucial and a score lower than 6 practically excludes the diagnosis, while a score above 8 very strongly suggests growing pains.

A result equal to eight points or above leads to a specificity of 100%, thus addressing the issue of the discordance of the prevalence

estimates of GP in previous studies. Indeed, researchers believe that part of the cases are falsely considered as such, because of problems in methodology<sup>3,9,10</sup>.

To the best of our knowledge this is the first attempt to quantify parental answers. A remarkable attempt to develop a diagnostic instrument for growing pains was made by Evans and Scutter<sup>6</sup>. However their approach was rather qualitative, as diagnosis was based on some core sentences asking parents directly about the diagnosis or about symptoms without rating the answers and proposing some sort of cut-off point. Our attempt was inspired by theirs and we tried to further develop and quantify an easy to use questionnaire.

### Limitations

The sensitivity and specificity of the present questionnaire were assessed on the condition that the diagnosis reported in the child's file was the right and final one. The prevalence of growing pains in this population based on orthopedics' examination was extremely high. This could be attributed to the fact that this study sample was not a general population sample, but rather a clinical one, as children were already complaining of lower limb pain. Other researchers had similar results when they studied lower limb pain in clinical settings<sup>11,12</sup>. Since in our study there was not any inclusion criterion concerning the frequency or the duration of limb pain, a longer follow-up period might lead the orthopedics to a different diagnosis.

In the future, it would be of great interest to further assess questionnaire's sensitivity and specificity in case-control studies, in clinical samples of rheumatology or oncology pediatric patients.

In conclusion, the proposed questionnaire, as far as we know, is the first attempt to quantify parental answers interviewed for their children's lower limb pain and to propose a cut-off value for diagnostic purposes. The questionnaire exhibits satisfactory internal consistency, is simple and it is easy to apply. It could be a useful and reliable diagnostic

tool contributing to the early detection of growing pains. It could help clinicians to their diagnostic approach without submitting the young patients to unnecessary laboratory investigations. Pediatricians and orthopedics could use it as an assistant tool when they speculate growing pains in a child and reassure the parents.

### Acknowledgments

I would like to express my very great appreciation to Dr George Krommydas, for assistance with the statistical analysis.

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## Appendix

### QUESTIONNAIRE

Class:.....

Age:.....

Gender: Boy o Girl o

Body weight:.....

Height:.....

Is your child complaining of leg pain (thighs, calves, soles) at an age over 3 years?

Yes  No  Do not know

Choose what best describes your child leg pain:

1. The pain is located:

- Inside muscle bulks (thighs, gluteal, calves, soles)
- Behind the knees
- Other/ do not remember / do not know

2. On the site of the pain:

- There is often redness or swelling
- It is very sensitive when touched
- There is limitation of movement
- There is recent injury
- Nothing is noted
- Do not remember / do not know

3. The duration of the pain is:

- Ten to 30 minutes
- 1-6 hours
- 6-12 hours
- >12 hours
- Do not remember / do not know

Please note as many of the following that describe the pain characteristics during the latest episode:

- |   | No | Yes | Don't<br>know |
|---|----|-----|---------------|
| 4. The pain is mostly present during late afternoon or night.                         |    |     |               |
| 5. The pain is still present next morning   |    |     |               |
| 6. The pain is bilateral.   |    |     |               |
| 7. The pain affects always the same leg.  |    |     |               |
| 8. The child cries due to pain.   |    |     |               |
| 9. The child awakes at night because of pain.   |    |     |               |
| 10. The child is otherwise well.  |    |     |               |
| 11. The pain resolves spontaneously or with massage of the affected area.             |    |     |               |
| 12. The pain subsides after taking an analgesic.                                      |    |     |               |
| 13. The pain is persistent and doesn't resolve.                                       |    |     |               |
| 14. The child has been complaining of pain on other sites for more than three months. |    |     |               |

In your opinion the pain relates to:

15. Athletic activities.
16. The weather.
17. Vigorous physical activity.
18. Rapid physical growth.
19. The type of shoes.
20. Platypodia (flat foot).
21. Emotional stress.
22. Particular joint flexibility.
23. Do you think that the pain is related to anything else?
24. Have you visited your pediatrician with the complaint of leg pains?
25. Has the child had any laboratory tests for the assessment of the pain?
26. Has your pediatrician referred to the pain as growing pains?
27. Have you or the other parent had leg pains during your childhood / adolescence?