Acta Derm Venereol 2015; 95: 78–82

CLINICAL REPORT

Haemangioma Family Burden: Creation of a Specific Questionnaire

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To develop and validate a specific questionnaire to assess burden on families of children with infantile haemangioma (IH): the Haemangioma Family Burden questionnaire (HFB). Items were generated from a literature review and a verbatim report from parents. Subsequently, a study was implemented at the Necker Hospital and the Pellegrin Children's Hospital for psychometric analysis. The HFB was refined via item reduction according to inter-question correlations, consensus among experts and exploratory factor analysis. A 20-item questionnaire, grouped into 5 dimensions, was obtained. Construct validity was demonstrated and HFB showed good internal coherence (Cronbach's α: 0.93). The HFB was significantly correlated with the mental dimension of the Short-Form-12 (r=–0.75), and the Psychological General Well-Being Index (r=–0.61). HFB scores differed significantly according to the size and localization of the IH. A validated tool for assessing the burden on families of children with IH is now available. ***Key words: burden; infantile haemangioma; questionnaire.***

Accepted Mar 12, 2014; Epub ahead of print Mar 25, 2014

Acta Derm Venereol 2015; 95: 78–82.

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Infantile haemangioma (IH) is a frequent benign vascular tumour, occurring in 3–10% of Caucasian infants (1−5). Approximately 60% of the lesions are located in the head and neck region (6−8). Complications may occur in 20% of cases, consisting of painful ulceration, functional impairment, disfigurement, and rarely, life-threatening respiratory distress or heart failure (8, 9). Although approximately 75% of IHs involute spontaneously by the age of 7 years (10, 11), in a number of children they persist during a critical period of psychological development (around the age of 10–12 years) (12).

Physical deformities in children can have a negative impact on health-related quality of life (HRQoL), social functioning and "self-concept", both in the children affected by vascular or other congenital malformations and their parents (13−16). Few studies have assessed such an impact in IH (10, 15, 17−19). In recent years the notion of "burden of disease" has taken an increasingly important place in the medical field in the evaluation of the care of chronic diseases (20−22). Based on an extensive literature review, no specific questionnaire focusing on the individual burden of families of children with IH has been published.

To assess patients', or families', HRQoL and individual burden, a self-administered questionnaire is the most relevant method of gathering data. However, burden questionnaires are still poorly developed, and there is, as yet, no methodological consensus for developing this type of tool. Previously available questionnaires for evaluating burden were established according to the methodology for developing HRQoL questionnaires (21, 23).

The aim of the current study was to design and validate a burden questionnaire for families of children with IH: the Haemangioma Family Burden questionnaire (HFB).

MATERIALS AND METHODS

The questionnaire was designed following standardized HRQoL questionnaire development and validation methodology (24, 25). A multidisciplinary team composed of healthcare professionals such as a physician, a nurse and a social worker, worked with the patients and their families. Creation and validation were the 2 main stages of this design process.

Questionnaire creation

This step was divided into 2 stages. The first stage included the creation of a verbatim report based on a literature review, interviews with healthcare professionals (paediatricians, dermatologists, nurses) and with the parents of children that have or have had IH of varying severity. Once the list of items had been produced, they were converted into questions. The questionnaire was created in a question and answer format. Response modalities were determined by consensus among the experts. Based on feedback from parents, 3 distinct modules were designed. In the first module, which was about family burden in daily life, 4 types of answer were fixed: "no without hesitation", "I don't know", "maybe" and "yes without hesitation"; answers were numbered 0–3. Furthermore, it was noticed that the severity of the disease may affect one family differently from another; a weighting module (module 2) has been designed in order to catch this different impact. Response modalities to these questions were: "positive impact", "no impact", "negative impact" and "I don't know"; scored –1, 0, 1, 0, respectively.

Finally, module 3 related to the child's daily life. Responses to these questions were: "yes without doubt" (scored 3),"maybe" (2), "no without doubt" (0) and "I don't know" (1).

The second stage consisted of a cognitive debriefing interview managed by a specialized institution (Lionbridge, Ireland). The aim was to guarantee comprehension of the original French questionnaire in terms of use of words and vocabulary, enabling a good understanding by all users (i.e. different socio-professional groups, durations of the disease, etc.) (26). A French native with a strong background in cognitive interviewing techniques conducted each interview. The questionnaire was discussed and modifications made if necessary. Respondents were sufficiently representative of the population for which the instrument was designed and the questionnaire was written in their first language.

A preliminary version of the questionnaire (HFB version 1.0) was consequently available.

Questionnaire validation

In this stage, a study aiming to reduce the number of questions and to validate the pilot questionnaire was implemented in 2 reference centres of IH in France (Necker Hospital, Paris; Pellegrin Children's Hospital, Bordeaux) between November 2011 and March 2012. Subjects who fulfilled the following inclusion criteria were asked to complete a questionnaire: parents of a child with IH; fluent in French; with oral consent for participation. The diagnosis of IH was based on clinical examination and on histological analysis when available. Thirty subjects were needed, as this number was validated in previous epidemiological studies (27). Seventy-five questionnaires were distributed and, of these, 58 were returned.

Parents completed the HFB version 1.0, and 2 validated non-specific self-administered questionnaires: the Short-Form 12-items v2 (SF-12) and the Psychological General Well-Being Index (PGWBI). The SF-12, a multipurpose short-form, results in an estimate of 2 HRQoL scores: Physical Component Summary (PCS) and Mental Component Summary (MCS). The higher the score, the better the HRQoL (28).The PGWBI consists of 22 items rated on a 6-point scale. It produces a self-perceived evaluation of psychological well-being expressed by a summary score, where a higher score indicates a better HRQoL (29). Furthermore, parents were asked to answer a series of questions on the IH of their child: the clinical IH history (age at diagnosis, type, location, size), its management (declaration of the diagnosis, treatment, cost, satisfaction) and its consequences (impact, disability). In order to evaluate the size of the IH, the multiple-choice responses were as follows: "very small"/"small", "rather large"/"large", "very large"/"extremely large". Three groups of severity were drawn according to the size. Finally, additional questions were asked to provide demographic and clinical information.

These questionnaires were completed by one of the patient's parents at their home and sent to the logistic centre using a prepaid envelope. Since these questionnaires were strictly anonymous, approval by an ethics committee was not considered necessary by the French administrative authorities.

Item analysis

In order to obtain the easiest possible questionnaire for use, some items, such as redundant ones, those that were highly correlated (only 1 item was retained) and non-pertinent items (those in which the majority of parents answered "no without hesitation") were removed from each module of the HFB version 1.0.

Psychometric properties were subsequently evaluated by assessing the construct validity, the internal consistency reliability, the concurrent validity and the discriminant validity of HFB.

Statistical methods for psychometric validation (Appendix S1[1])

RESULTS

Questionnaire creation

After the interviews with parents, a multidimensional questionnaire comprised 36 questions was drawn up by the working group (HFB version 1.0). The first module, focusing on the individual burden for families of children affected by IH, comprised 18 questions, the second module comprised 12 questions and the third module comprised 6 questions.

During the cognitive debriefing interview, a few questions were modified to make them easier to understand. In most cases only the word order was changed.

Questionnaire validation

Study population. A total of 75 parents were included in the study, 58 (77.3%) of whom returned their questionnaire to the logistics centre. Children with IH had a mean age ($\pm$ standard deviation; SD) of 9.3 ± 4.8 months; mean age at diagnosis was 2.3 ± 2.0 months. Questionnaires were completed a mean of 6 months after the diagnosis. Demographic and clinical characteristics of the children are shown in Table I.

With the exception of 1 case, psychological support was never spontaneously proposed. The information provided concerning the disease appeared to be clear in 80.0% of cases, but was sufficient for only 60.0% of families. The information concerning treatment was clear for 82.0% of cases and sufficient in 75.0%. Of the respondents, 77.2% reported that they had received medical advice; 59.6% of the advice was about daily care, 42.0% concerned management and 8.0% was administrative advice. Replies showed that 45.6% considered their child's disease as a disability, and 64.9% said they had to contend with the judgement of others. In addition, 71.9% exhibited anxiety concerning recovery, 26.0% had feelings of guilt, 14.0% felt discouragement, and 17.5% had feelings of incomprehension. IH affected nearly 60.0% of respondents' jobs: 10.5% decreased their work time, 30% took sick leave (repeated in 21.1%, rarer in 8.9%), 8.8% requested parental leave, and 10.5% took days off. With regard to care, 92.9% of respondents said they were satisfied overall.

Item analysis. Analysis of the responses of the 18 questions of module 1 did not lead to extensive modifications: only one question was removed because it was highly correlated with other questions ($r > 0.8$). Among the 12 questions in module 2, 7 were removed. Indeed, all of the questions expressed the same concept as some of module

[1]https://doi.org/10.2340/00015555-1847

1. In the end, it appeared that module 3 did not fully express burden, since it was more about the child's attitude. It was then decided to analyse these questions separately and not to include them in the HFB questionnaire.

Construct validity and internal consistency reliability. Based on the result of exploratory factor analysis performed on module 1, one item was removed due to cross-loading on factors; another one due to the absence of correlation with the factors. The 5-group model was then the most parsimonious. Consequently, according to the standardized regression coefficients, each group of questions was assigned a dimension: "Family life" (4 questions), "Relationship and Work" (3), "Emotions/Feelings" (3), "Psychological" (3) and "Disease management" (2) (Table II).

With regard to reliability, Cronbach's α was 0.93. This indicated good internal coherence.

Concurrent validity. Analysis of the SF-12 highlighted an alteration in the mental HRQoL dimension (40.5 ± 11.3), but not in the physical dimension (54.9 ± 5.1). The HFB score showed a significant inverse correlation with the mental dimension of the SF-12 ($r = -0.75$; $p < 0.0001$), but it was not significantly correlated with the physical dimension ($r = -0.20$; $p = 0.1647$). The HFB score was also correlated with the PGWBI global score (–0.61; $p < 0.0001$).

Discriminant validity. The mean HFB score was 20.7 ± 18.8 [range 0–61.6]. According to the size of IH, HFB scores differed significantly (Fig. 1). Indeed, HFB score was significantly higher for parents of child with "very large"/"extremely large" IH than parents of child with "very small"/"small" IH (Fig. 1). In addition, parents of child with one localization of IH had a significantly lower score than parents of child with 2 or at least 3 localizations (9.8 ± 10.8 vs. 25.7 ± 20.9 vs. 33.3 ± 15.5). Parents of child with at least 1 IH on the head or neck had a significantly higher score than the others (23.3 ± 19.2 vs. 13.0 ± 15.6, respectively; $p = 0.0481$). Parents who considered the IH of their child as a disability had also a higher score on the HFB than the others (28.5 ± 17.5 vs. 13.7 ± 17.3, respectively; $p = 0.0012$).

Table I. *Demographics and clinical characteristics of patients (*n = *58)*

Characteristic	
Age, months, mean ± SD [range]	9.3 ± 4.8 [2–23]
Age at diagnosis, months, mean ± SD [range]	2.3 ± 2.0 [0–9]
Parent who completed the questionnaire, *n*[a] (%)	
Mother	31 (63.3)
Father	18 (36.7)
Infantile haemangioma subtype, *n*[b] (%)	
Superficial (cutaneous)	21 (38.2)
Deep (subcutaneous)	14 (25.4)
Mixed	20 (36.4)
Number of localizations, *n* (%)	
1	24 (41.4)
2	23 (39.7)
≥3	11 (18.9)
Localization of infantile haemangioma, *n*[c] (%)	
Head and neck	43 (74.2)
Eye	16 (27.6)
Ear	3 (5.2)
Lip	3 (5.2)
Body	25 (43.1)
Arm	8 (13.8)
Hand	4 (6.9)
Leg	7 (12.1)
Trunk	5 (8.6)
Genitals	4 (6.9)
Size of infantile haemangioma, *n* (%)	
Very small/small	19 (32.8)
Rather large/large	27 (46.5)
Very large/extremely large	12 (20.7)

[a]Nine parents did not complete this item; they were counted as missing data. [b]For this question 3 data were missing. [c]Multiple answers possible.

DISCUSSION

The notion of burden was introduced by the World Health Organization (WHO) (20) and is useful in quantifying the health of a population and determining priorities of action in the public health domain. The notion of individual burden of disease was introduced to define "disability" in a broad sense (psychological, social, economic, physical), and to distinguish it from societal burden, which is primarily concerned with economic impact.

Few studies have assessed psychosocial impact, HRQoL, behaviour and social functioning in patients with IH (10, 15, 17−19). Hornweeg et al. (18) studied HRQoL in 236 children and their families with a specific HRQoL questionnaire designed for their study. They showed that negative effects are more important when complications are present or when the IH is located on a visible part of the body. This study also emphasized the necessity for a specific questionnaire (18). Results of other reports showed a psychological impact on parents, with an increase in stress, anxiety and a possible impact on social relationships and between children and parents. No change in the child's behaviour was found (19). The relatively high frequency of IH in young children, its potential aesthetic impact, the complications that can ensue, and previous studies on HRQoL suggest that an evaluation of the individual burden on families of affected children is necessary in order to improve medical care.

This study devised a specific questionnaire, which has been validated and which is in accordance with the recommendations for the creation of HRQoL questionnaires. This new tool, the HFB, comprises 20 items. The overall score of the HFB was found to be highly and statistically correlated with the mental component of the SF-12 and with the PGWBI, which confirm the external validity of the questionnaire. The score of the physical dimension of the SF-12 did not suggest an impairment of HRQoL, as the correlation of the HFB with this dimension was not significant. Because the HFB is a burden questionnaire for families and not for

Table II. *Standardized regression coefficients from the final rotated factor pattern. Regression coefficients shown in bold represent the individual items that were included in each dimension*

	Factor 1: Family life	Factor 2: Relationship and work	Factor 3: Emotion/ feeling	Factor 4: Psychological	Factor 5: Disease management
Our child's haemangioma has made us question our future plans	**0.41208**	0.34054	–0.02313	–0.09376	0.26729
My child's haemangioma complicates our family life	**0.83593**	–0.03915	0.16841	–0.00611	0.05397
Our child's haemangioma puts a big strain on my relationship with my partner	**0.91864**	–0.06091	0.03268	0.10648	–0.04388
My child's haemangioma has turned my life upside down	**0.43753**	0.08412	0.07752	0.30841	0.11299
We sometimes spend less time with our other children because of our child's haemangioma	–0.09798	**0.79641**	0.07132	0.00897	0.19830
My child's haemangioma has had an effect on my career	0.20250	**0.76200**	0.02283	–0.02456	–0.02630
I have had to stop work because of my child's haemangioma	–0.07201	**0.73486**	–0.07153	0.12522	–0.09512
My child needs a lot of affection because of his/her haemangioma	0.02186	0.16272	**0.48736**	0.36161	0.01552
My child's haemangioma makes him/her more vulnerable than others	0.02937	–0.14718	**0.81334**	0.12973	0.09027
My child needs more attention than others because of his/her haemangioma	0.11176	0.09184	**0.83882**	–0.12098	0.01918
I am protective of my child because of his/her haemangioma	–0.06729	0.14895	0.39414	**0.53193**	–0.07359
Peoples' reactions to our child's haemangioma weigh me down	0.06852	–0.10061	0.01730	**0.65546**	0.28041
I feel guilty because of our child's haemangioma	0.15044	0.26737	–0.05875	**0.65672**	–0.13947
I often feel frustrated after seeing doctors about our child's haemangioma	0.35561	–0.03410	–0.12479	0.35625	**0.42324**
I have come to terms with our child's haemangioma	0.10417	0.00058	0.17733	–0.00897	**0.63855**

children, it was not surprising that the physical dimension assessed in parents was not altered. Other studies assessing the HRQoL of parents of children affected by cutaneous diseases using the SF-12 and a more specific questionnaire found the same result regarding the physical dimension of the SF-12 (31).

The discriminant validity of the HFB is supported by the significant differences highlighted between groups, such as the size of the IH, its localization, and the number of localizations. Indeed, a large visible IH or IH on the head and neck resulted in a greater burden.

Limitations associated with the current study include the fact that the size of the IH was assessed by the parents themselves, and thus was a subjective assessment. Psychometric analysis was conducted in a relatively small sample of parents. In addition, only 2 French reference centres participated in this validation process. This probably led to higher recruitment of more severe or extended cases of IH. However, the wide variety of patients seen in both of these centres reduced this limitation. Further validation is required. In order to assess the interpretability of HFB, it is necessary to evaluate the questionnaire's sensitivity to clinically meaningful change or minimally important difference in a prospective cohort study. Reproducibility of the questionnaire should also be assessed. Confirmatory factorial analysis on another sample may be necessary to confirm the factorial structure of HFB. Finally, no handling of missing data was done in this study. Missing data is a problem in multi-item instruments, and numerous methods are available for handling them (32). The design of future studies to confirm the utility of HFB should incorporate appropriate methodology for handling missing data. Finally, the pilot questionnaire was developed and validated in French; however, linguistic and cultural validation, according to current good practice guidelines for translation of a HRQoL questionnaire (26), was performed in US and UK English, Spanish, Italian and German; the questionnaire is currently being tested in a larger international study.

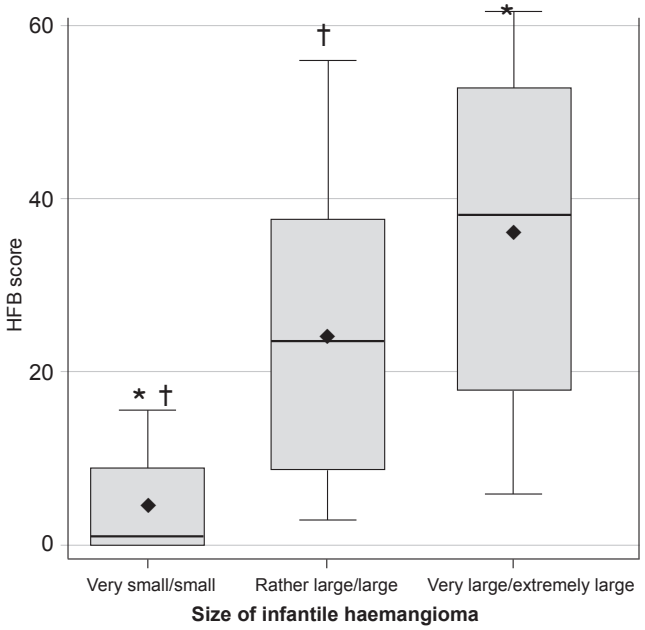

Fig. 1. Box-and-whisker plot of Haemangioma Family Burden questionnaire (HFB) scores according to the size of the infantile haemangioma. *Significant difference; $p < 0.0001$. †Significant difference; $p < 0.0001$.

The benefit of this questionnaire is that it evaluates the family's feelings about the burden on the family, which takes into account HRQoL, integration within the community, life organization and the level of medical resources used. The questionnaire can also be used to evaluate treatments. Burden evaluation could improve communication and exchange of information between practitioners and patients or their families, create an opportunity for the practitioner to better know and manage problems not spontaneously brought up by the patients

or parents, and facilitate continuity of care through documentation of patient follow-up between visits. Burden evaluation could also improve compliance, satisfaction with care, management of the disease and the feeling of being taken into consideration. Reducing the burden of disease is an important issue in patient management.

ACKNOWLEDGEMENT

The HFB questionnaire is available on request from Mapi Research Trust (Table SI[1]).

Conflicts of interest: Dr Taieb is employed by Pierre Fabre.

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