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Evaluation of efficacy and feasibility of foot reflexology in children experiencing chronic or persistent pain.

Evaluation de la faisabilité et de l'efficacité de séances de réflexologie plantaire sur les douleurs prolongées et chroniques en pédiatrie.

Short title: Efficacy of foot reflexology in children experiencing chronic or persistent pain.

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ABSTRACT

Background: Complementary and Alternative Medicines (CAM) are increasingly used in the therapeutic arsenal, particularly for pain management. Foot Reflexology (FR) is still poorly evaluated, specifically in the pediatric population. The aim of this study was to evaluate the effectiveness of FR sessions in children experiencing chronic or persistent pain. **Methods:** We conducted a prospective study in two pediatric centers from January 2011 to January 2014. Sessions of FR were offered to children regardless of their age, experiencing persistent pain (> 72h) or chronic pain (> 3 months). A form was completed by the patient before and after each FR sessions. The effectiveness of the session was evaluated using a Visual Analogue Scale (VAS) for both pain and anxiety. **Results:** One hundred and twenty-two patients suffering from persistent pain were included. We observed a significant decrease of mean VAS pain scores after each session (respectively $P < 0.001$, $P < 0.001$ and $P = 0.015$) and of mean VAS anxiety scores ($p < 0.001$) for all sessions). Seventy patients suffering from chronic pain were included. Decrease in VAS pain scores was statistically significant after each reflexology session for children suffering from headache and musculoskeletal pain ($p < 0.001$). Anxiety was significantly lower after each session ($p < 0.001$). **Conclusion:** In 192 pediatric patients, FR significantly reduce pain and anxiety in children suffering from persistent or chronic pain. This CAM could have a place in pain management in children but needs to be evaluated in larger cohorts.

KEYWORDS: Complementary and alternative medicines; Foot reflexology; Children; Pain; Anxiety

RESUME

Introduction : les thérapies alternatives et complémentaires font partie intégrante de l'arsenal thérapeutique, notamment dans la gestion des douleurs. La réflexologie plantaire (FR) reste une discipline sous-évaluée, spécifiquement en pédiatrie. L'objectif de cette étude était d'évaluer l'efficacité de la FR chez des patients pédiatriques souffrant de douleurs chroniques ou persistantes. **Méthodologie :** nous avons conduit une étude prospective dans 2 centres sur 3 ans. Les séances de FR

étaient proposées à tous les enfants souffrant de douleurs prolongées (>72h) ou chroniques (> 3 mois). Un questionnaire anonyme était rempli par chaque patient avant et après la séance. L'efficacité des séances était évaluée par une échelle visuelle analogique (EVA) pour la douleur et l'anxiété. **Résultats** : Cent vingt-deux patients ont été inclus dans le groupe « douleurs persistantes ». Il a été observé une diminution significative de la moyenne des EVA douleur après chaque séance (respectivement $P < 0.001$, $P < 0.001$ and $P = 0.015$) et de la moyenne des EVA anxiété ($p < 0.001$) pour toutes les séances). Soixante-dix patients ont été inclus dans le groupe « douleur chronique ». La moyenne des EVA douleur était significativement diminuée après chaque séance pour les patients souffrant de céphalées et de douleurs musculo-squelettiques ($p < 0.001$). La moyenne d'EVA anxiété était significativement diminuée pour tous les patients après chaque session ($p < 0.001$). **Conclusion** : sur 192 patients pédiatriques souffrant de douleurs persistantes ou chroniques, la FR permet de diminuer significativement la douleur et l'anxiété. Cette thérapie pourrait avoir une place importante dans la gestion de la douleur chez l'enfant.

MOTS-CLES : thérapies alternatives et complémentaires ; réflexologie plantaire ; pédiatrie ; douleur ; anxiété

INTRODUCTION

Complementary and alternative medicines (CAM) are care techniques encouraging a global approach of the patient. Their aim is to treat specific symptoms such as gastro-intestinal disorders, pain or anxiety in order to improve quality of life (1). CAM are increasingly used in the current context of global patient care, especially in oncology. Previous studies have shown that 75% of patients suffering from cancer experience pain (2) and that 31 to 36% of these patients use CAM (2–4).

However, before offering CAM on a systematic basis to patients, it is absolutely necessary to establish the effectiveness of such practices. More and more physicians initiated studies to prove this effectiveness, but previous studies often concern small sample sizes and have major methodological limitations (5–9).

Foot reflexology (FR) is an ancestral manual therapy derived from Chinese medicine. It consists of the systematic application of pressure to specific reflex points on the foot in order to promote homeostasis. Working from the premise that reflex areas in

the foot are linked to principal organs and glands via energy zones, it is believed that the application of pressure to these areas releases congestion and promotes a flow of energy through the body (10,11). By enabling optimal circulation, helping to eliminate toxins, and supporting the major systems of the body (immune, nervous, and glandular), FR is thought to restore balance.

This CAM is still poorly evaluated, specifically in pediatric population (12).

The aim of this study was to describe the practice of FR in children suffering from chronic or persistent pain from January 2011 to January 2014. Secondary objectives were to evaluate the effectiveness of FR sessions on chronic or persistent pain, on anxiety, and the satisfaction of patients and their families.

MATERIALS AND METHODS

Study design

Considering the subjective characteristics of data collection (VAS, characteristics of pain,...), a prospective design seemed to be more accurate and more statistically significant (13). We conducted a prospective cohort study in two pediatric centers, where FR had been performed for several years, during 3 years. One is a Cancer center where children are treated for solid tumor and leukemia, and the other one is a chronic pain management center. A different nurse trained in FR offered her sessions in each center. Nurses have been trained in the same French school E.T.R.E (Ecole des Techniques en Reflexologie). This school has received the agreement of the French Federation of Reflexology (FFR). The nurses have benefited from a 372h training and have obtained the French certificate of Reflexology.

Data collection was performed prospectively, for every session, from January 2011 to January 2014.

Patients

FR sessions were proposed upon medical prescription to all children, adolescents and young adults under 25 years-old experiencing pain treated in each center. Children were recruited either at the chronic pain clinic or during an in-patient stay for persistent pain in cancer unit. All children who benefited from a foot reflexology session were proposed to participate in the study without limit of age. Children and their families were orally informed of the aim of the session and of the data collection. Persistent pain was defined as a pain lasting more than 72h. Chronic pain was defined as a pain lasting over 3 months.

Exclusion criteria were limited to FR contraindication: thromboembolic risk, local infection or recent lower limb surgery.

Data collection

A form was completed before and after each FR sessions by the child if applicable or with his parents' help. Some data were completed by the nurse with medical information obtained from the patient medical file. Once completed, the form was deposited anonymously and analyzed by an independent Clinical Research Associate.

Multiple Choice Questions (MCQ) assessed the characteristics of the pain, presence of anxiety, sleep or digestive disorders. Personal and family history, center of interest, use of analgesic drugs, and existence of an ongoing non-drug therapy (as psychological, sophrology, relaxation, hypnosis, or other) were also collected.

The child or their parents evaluated their pain and anxiety by using Visual Analogue Scale (VAS) before and after the session (14–16). According to patients' capacity of using VAS scale, this tool was used either in self-evaluation or as a proxy-reporting

tool, as reported previously in the literature (17–20). Reactions of the patient during the FR session (relaxed, let go, yawning, sleepiness, drowsiness, gratitude, silence, tension or other) were recorded by the nurse practicing FR sessions. Parents' opinion about the FR session was also collected. Data collection was repeated with the same methodology during a second and a third session.

[Statistical methods](#)

Data analysis was performed using R software for Windows, version 3.1.0. i386. Qualitative data were presented in terms of associated frequencies and percentages. They were compared by Pearson Chi2 test or by Fisher exact test. Quantitative data were described by number of patients, mean and standard deviation. Means were compared by Student's t test. The level of significance was $P < 0.05$.

[Ethical consideration](#)

This study was declared to the Comité National Informatique et Liberté (CNIL, registration number 1838927). Data were anonymized. Due to the observational nature of our study, the ethics committee agreed not to declare our study.

RESULTS

[“Persistent pain” population](#)

Description of the population

One hundred and twenty-two patients suffering from cancer were included during a hospitalization for a pain exacerbation due to their oncologic pathology itself or secondary to treatment. Data are summarized in Table 1.

Mean age was 11.7 years (6months to 21yrs). Sixty-four patients (52.5%) were male. Fifty-three children (43.4%) had previous or concomitant psychological counselling, 31 (25.4%) sophrological counseling, 8 (6.6%) benefited from hypnosis sessions and 5 (4.1%) used TENS (Transcutaneous Electric Nerve Stimulation).

Regarding functional complaints, 95 children (85.6%) presented anxiety, 56 (45.9%) sleep disorders, 39 (54.9%) nausea and/or vomiting, 70 (77.8%) diarrhea or constipation, 51 (70.8%) abdominal pain (Fig.1).

Effectiveness on pain

VAS pain scores were evaluated in 67/122 patients after a first session, 20/42 after a second and 10/17 after a third session. VAS could not be performed in the other patients because of their age. We observed a significant decrease of mean VAS scores after each session (respectively $P < 0.001$, $P < 0.001$ and $P = 0.015$). (Table 2).

Effectiveness on anxiety

Anxiety was evaluated in 56/122, 19/42 and 11/17 patients respectively after the first, the second and the third FR sessions. The decrease in the mean of VAS anxiety scores was significant after each session ($P < 0.001$ for all sessions). (Table 3).

“Chronic pain” population

Population description

Seventy patients treated in a chronic pain management center received FR sessions and were included. Data are summarized in Table 1.

Mean age was 13 years (6 yrs to 18 yrs). Fifty-six patients (80%) were female. Reason for consultation was headache for 27 patients (38.6%), abdominal pain for 12 patients (17.1%), musculo-skeletal pain for 29 patients (41.4%) and algodystrophy for 2 patients (2.9%). Fifty-nine children (84.3%) had previous or concomitant psychological counselling, 6 (8.6%) sophrological counseling, 3 (4.3%) benefited from hypnosis sessions and 20 (28.6%) used TENS.

Regarding functional complaints, 65 children (92.9%) presented anxiety, 48 (68.6%) sleep disorders, 7 (10%) nausea and/or vomiting, 14 (20%) diarrhea or constipation, 51 (70.8%) abdominal pain (Fig.1).

Effectiveness on pain

Decrease in VAS was statistically significant after each reflexology session for children suffering from headache and musculoskeletal pain ($p < 0.001$). It wasn't significant for children suffering from abdominal pain (Table 4).

Effectiveness on anxiety

Decrease in anxiety after each of the three sessions was statistically significant for all children ($p < 0.001$). (Table 3).

Overall outcome

Among the 191 evaluated patients, 70 fulfilled the last part of the questionnaire dedicated to global evaluation of the FR sessions. Sixty-five of them (93%) felt a feeling of relaxation after a session. Fifty-seven of 67 answering patients (85%) reported an improvement of quality of sleep. Sixty-seven of 72 patients (93%) and 68 of 71 parents (96%) were satisfied with the sessions. Subjectively, 31 of 36 responding children (86%) noted an improvement of their quality of life.

DISCUSSION

FR is one of the less evaluated CAM. Only a few randomized trials report its benefit in back pain (21), or dysmenorrhea (22). Bao et al (2) described that FR could be beneficial as an analgesic therapy, but with a low level of evidence.

There is very few published study on FR in pediatric population (12). FR is particularly interesting in this population because of its non-invasive character. Moreover, it does not interfere with the patient privacy; it can be practiced in every room, and requires no special equipment. Thus, evaluation of its effectiveness is relevant.

This cohort of 192 children is the largest reported, thus allowing bringing out a statistical effectiveness of FR for pain and anxiety management in children suffering from persistent or chronic pain. We noted a significant decrease in pain score after each session. Unfortunately, since most of children benefited from a single session, we were not able to evaluate the benefit of repeated sessions. However, children who were able to experience more than one session, reported the same VAS before each session, confirming a short-term effectiveness of FR. Such data has been previously described (23) with a pain reduction immediately after the FR session but not maintained over 24 hours.

Regarding patients suffering from chronic pain, we demonstrated a significant decrease in VAS pain score after the FR sessions, except for children suffering from abdominal pain. However, since abdominal pain is often multifactorial, it is difficult to conclude an inefficiency with so few patients.

Several studies failed to highlight a significant difference between FR and a non-specific massage (10,11). This may be due to the psychological aspect of these two approaches. As in our study, patients could feel better after the FR sessions because they received personally private care, as a placebo effect. The psychological component of pain is undeniable, and therapies should consider it. Batalha et al published in 2013 promising results about the use of massage for the treatment of pain in children with cancer (24). This study revealed a significant decrease in pain after each massage session. However, probably due to the small sample size, the authors only managed to demonstrate a significant effect on perambulation capacity compared with a control group.

Positive effects of FR on anxiety have been described in several studies. Sharp et al (25) conducted a randomized controlled trial including 183 women with breast cancer

who had recently received surgery. Compared to a self-initiated care, FR and massage had a statistically significant effect and on quality of life. Similarly, a study conducted by Quattrin et al (26) demonstrated that FR sessions could significantly reduce the anxiety of patients undergoing treatment for cancer. However, as in our study, effectiveness on anxiety may be partially explained by effectiveness on pain, particularly on chronic pain.

In this pediatric population, FR sessions appeared to significantly reduce anxiety even if such effect was not prolonged in time.

Patients and parents satisfaction of FR sessions was evaluated. However, such data was only recorded for patient with persistent pain, therefore not allowing statistical analysis. However, a large majority of parent and patients were satisfied with the sessions in term of pain reduction and improvement of quality of life.

This study has a few methodological limits. First, this is a non-randomized observational study. However, randomized clinical trials in order to evaluate effectiveness of these practices are difficult to manage, particularly in pediatric population. The methodology of pain and anxiety assessment could also be discussed. Indeed, we have chosen to use a VAS for these two items. VAS is validated for pain assessment in children > 6 years but could also be used as a proxy rating tool (by parents or caregivers) for younger (16,27). Regarding anxiety, this methodology is only described for children > 6years (17). As we didn't expect to include very young children in our study, we hadn't planned to use a specific scale for anxiety heteroevaluation and decided not to exclude the 22 children younger than 6years of our analysis being aware of the risk of lost information.

In order to avoid any bias, children and their parents were asked to answer the questionnaire alone and the form was returned anonymously. Although our study

reported very few side effects of the FR sessions, the follow up time is very short. Overall FR is a non-invasive alternative therapy and we can assume that it has fewer side effects than analgesic drug therapies.

This study aimed to observe the feasibility of FR sessions, before to demonstrate its effectiveness. So we did not collect the concomitant medications, especially painkillers, which can induce some bias.

In conclusion, in this prospective observational study, we showed that in 192 patients, FR significantly reduced pain and anxiety in children suffering from persistent or chronic pain. This CAM could have a place in pain management in children but needs to be evaluated in larger cohorts.

ACKNOWLEDGMENTS

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LIST OF NON-STANDARD ABBREVIATIONS

Complementary and alternative medicines (CAM)
Foot reflexology (FR)
Multiple Choice Questions (MCQ)
Visual Analogue Scale (VAS)
Transcutaneous Electric Nerve Stimulation (TENS)

CONFLICT OF INTEREST STATEMENT

The authors declare no conflicts of interest

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TABLES AND FIGURES

Table 1 : Patient characteristics (n=192)

Sd : standard deviation ; n: number of patients; TENS: transcutaneous electro-neurostimulation

Table 2: VAS of pain before and after each session for patients experiencing persistent pain

Sd : standard deviation ; n: number of patient

Table 3: VAS of anxiety after and before each session

**P<0.001; sd : standard deviation ; n: number of patient*

Table 4: VAS means of pain before and after each session for patients experiencing chronic pain

**P<0.001; sd : standard deviation ; n: number of patients*

Fig. 1: Complains related with pain in the two groups (persistent pain and chronic pain)

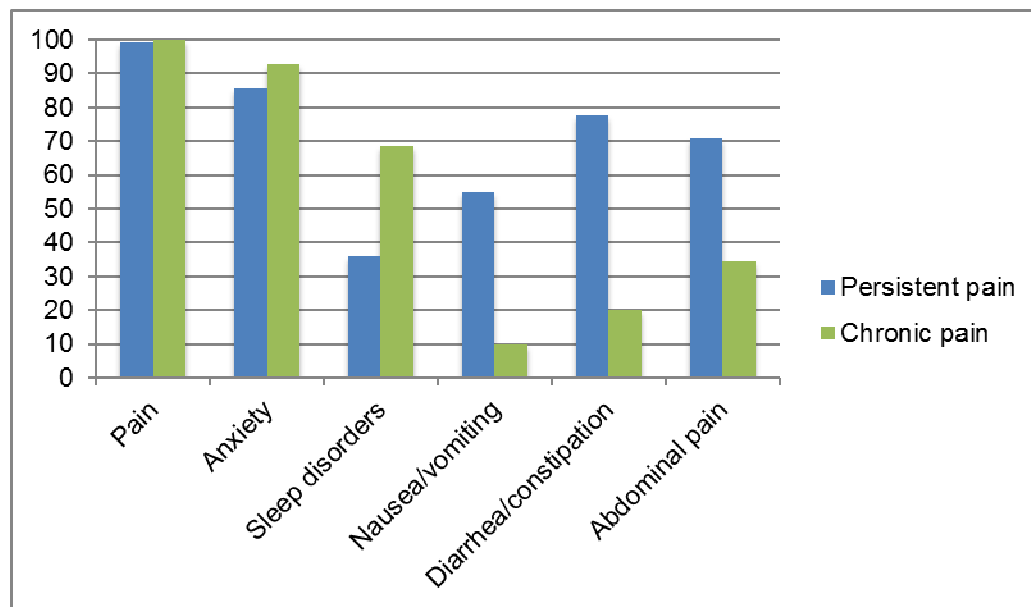


Fig. 1: Complaints related with pain in the two groups (persistent pain and chronic pain)

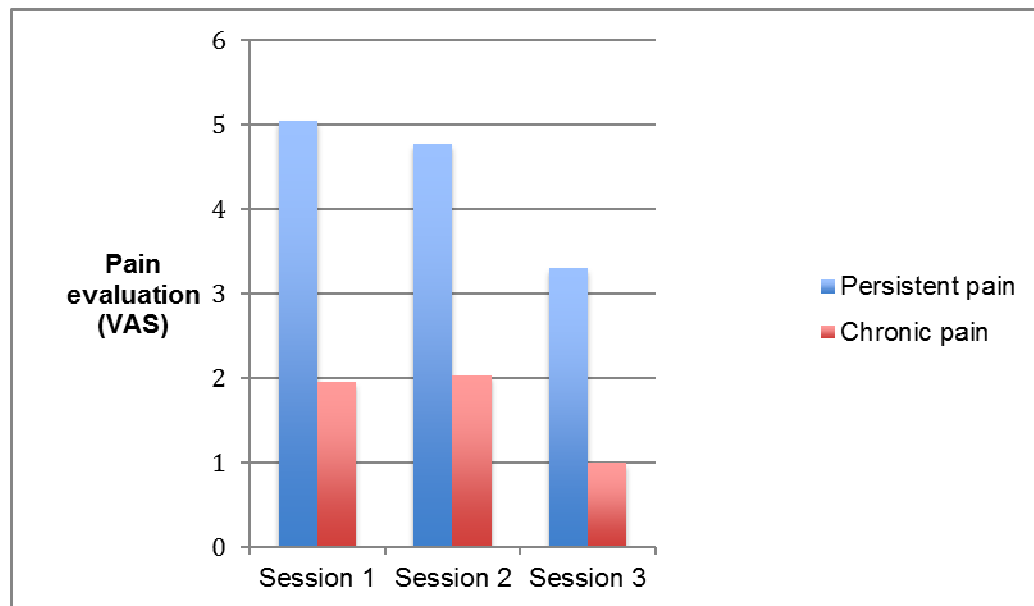


Fig. 2: VAS of pain before and after each session for patients experiencing persistent pain

Table 1 : Patient characteristics (n=192)

Sd : standard deviation ; n: number of patients; TENS: transcutaneous electro-neurostimulation

		Persistent pain	Chronic pain
Age (mean, sd)		11.7 (5.0)	13.0 (2.9)
Gender (n,%)	Male	64 (52.5)	14 (20)
	Female	58 (47.5)	56 (80)
Ongoing follow-up (n,%)	Psychology	53 (43.4)	59 (84.3)
	Sophrology	31 (25.4)	6 (8.6)
	Hypnosis	8 (6.6)	3 (4.3)
	Osteopathy	0	2 (2.8)
	TENS	5 (4.1)	20 (28.6)
Etiology (n, %)	Cancer (curative)	92 (75.4)	0
	Abdominal pain	9 (7.4)	12 (17.1)
	Vaso-occlusive crisis	7 (5.7)	0
	Postoperative	7 (5.7)	0
	Headache	3 (2.5)	27 (38.6)
	Cancer (palliative)	1 (0.8)	0
	Musculoskeletal pain	0	29 (41.4)
	Algodystrophy	0	2 (2.9)
	Other	3 (2.5)	0

Table 2: VAS of pain before and after each session for patients experiencing persistent pain

Session	Before session (mean, sd)	After session (mean, sd)	<i>P</i>
1 (n=67)	5.05 (2.15)	1.96 (1.68)	<0.001
2 (n=20)	4.78 (2.60)	2.03 (2.23)	<0.001
3 (n=10)	3.3 (2.91)	1.0 (2.00)	0.0147

Sd : standard deviation ; n: number of patient

Table 3: VAS of anxiety after and before each session

Session	Persistent pain		Chronic pain	
	Before session (mean, sd)	After session (mean, sd)	Before session (mean, sd)	After session (mean, sd)
1	6.3 (1.8)*	1.9 (1.7)*	8.1 (3.8)*	3.8 (2.9)*
2	6.3 (2.2)*	2.5 (1.6)*	6.9 (3.0)*	3.6 (2.6)*
3	6.0 (1.6)*	2.3 (1.7)*	8.2 (4.0)*	3.4 (2.7)*

**P<0.001; sd : standard deviation ; n: number of patient*

Table 4: VAS means of pain before and after each session for patients experiencing chronic pain

Session	Headache		Musculoskeletal pain		Abdominal pain	
	Before session (mean, sd)	After session (mean, sd)	Before session (mean, sd)	After session (mean, sd)	Before session (mean, sd)	After session (mean, sd)
1	6.7 (4.6)*	3.6 (2.7)*	5.2 (3.2)*	3.7 (2.5)*	3.8 (2.4)	3.7 (2.8)
2	6.9 (4.4)*	3.8 (3.2)*	6.0 (3.3)*	4.8 (3.4)*	2.8 (1.9)	2.9 (1.8)
3	5.6 (3.7)*	3.9 (2.6)*	5.8 (3.8)*	5.2 (3.2)*	3.9 (2.8)*	2.4 (2.0)*

* $P < 0.001$; sd : standard deviation ; n: number of patients