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CASE REPORT

Compliance to Compression Therapy Measurement, where are the Needs? Results of an International Survey

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Abstract

Introduction: Compliance is the cornerstone of compression therapy in chronic disorders. The use of self-administered questionnaires is a standard way of measuring compliance. However, these questionnaires are not validated. Improving measurement would involve using sensors into the textile. The question of the need of such sensors by the medical community is addressed.

Methodology: 15 items online questionnaire targeting compression therapy opinion leaders who were asked to express their need for devices allowing to report wearing time of compression therapy in clinical trials.

Results: Forty-two questionnaires were analysed. 57.5% (23/40) were from France. 72.2% (26/36) of the respondents trust the patient self-reporting adherence. Fifty-five percent (18/33) agree that the self-evaluation method is satisfying and fulfil their needs. Concerning the availability of an adherence monitoring device that could be used in clinical trials, 88% (29/33) of responders would be interested to use it and 91% (30/33) found that it could improve the quality of the clinical trials.

Conclusion: This international survey shows that for majority of respondents the use of not validated self-administered questionnaires fulfils their need when it is needed to measure compliance of compression therapy in clinical trials. Nevertheless, they found that the use of sensors would improve the quality of studies.

Keywords: Compliance; Sensor; Compression Therapy; Medical Compression stockings.

Introduction

Compression therapy is a key treatment to various acute or chronic disorders mainly of venous origin [1,2]. Compliance with compression therapy in chronic venous disorders is considered low when referring to the wearing time recommendations of national or international consensus [5,6]. Long term compliance to compression remains poor regardless of the disease, from not complicated varicose veins to ulcer, although somewhat higher when the clinical severity is greater [7,10].

The first key point when talking about compliance is to measure it. In more than 90% of trials involving compression therapy and using stockings, when compliance was measured, self-reporting questionnaire were used. All but one of these questionnaires, were not validated, which means that they did not meet the methodological process of internal and external validations [11]. Consequently, the reporting of compliance of compression therapy could have been biased in most studies. The valid questionnaire was published in 2019 and made freely available to any researcher since then and yet has not been used in studies yet. The reason why investigators prefer their own home-made unvalidated questionnaire is unknown.

Would other means be more accepted by researchers?

In addition to questionnaires, sensors included in fabric were developed and recently tested, to record a more reliable wearing time, being able to approach more acutely the dose-response effect of compression therapy in various medical indications [12,13].

Despite the improvements represented by a validated questionnaire or reliable sensors, their usage remains low especially if we consider the few requests for sensors made towards manufacturers.

One possible reason is that investigators do not need improvements in this field and, in spite of limitations, found that not validated home-made questionnaire are reliable enough.

In order to test the two following hypothesis:

1) Investigators are satisfied enough with home-made questionnaires,

2) They do not need electronic tools to improve measurement of compliance to medical compression stockings

a survey was elaborated addressing these two main questions to opinion leaders in the field of compression therapy.

Material and Method

Design

On-line questionnaire targeting compression therapy opinion leaders on their need for devices that report wearing time of compression therapy in clinical trials.

Questionnaire

It was a 15 questions questionnaire including 12 single choice questions, 2 multiple choice and one open question. For the 12 single choice questions, the respondent could leave a comment.

The questionnaire was divided in four parts, the first one with 2 questions addressing the profile of the respondent, the second part titled “the state of the art of clinical trials involving medical compression” comprised 4 questions and investigated the reliability of the self-reporting questionnaire used in the studies, the third part named « interest for an adherence monitoring device” addressed the interest of a device to be used in studies with 3 questions and the fourth part, “Device features” was about the wishes of the information collected by the device itself with 6 questions (Annex 1).

Procedure

Sigvaris is one of the major textile manufacturers and provider of compression therapy worldwide.

Key opinion leaders on compression therapy were defined as medical doctors identified by Sigvaris as experts on compression therapy whatever their practice, private practice or not, having or able to carry out trials on compression.

Key opinion leaders on compression therapy who fulfil the above definition, were contacted by each subsidiary company of Sigvaris, informed about the questionnaire and invited to fill it in. It was specified that it took 10 minutes to complete. The questionnaire was available on-line for 2 months.

Results

General

42 questionnaires were analysed. 57.5% (23/40) were from France, 20% (8/40) from Brazil. Seventy four percent (29/39) of the responders had at least participated to or headed one clinical trial (Table 1). For an unknown reason, key opinion leaders from North America were not contacted.

Table 1: Worldwide distribution of the 40 participants of the international survey about the need of devices in reporting the wearing time of compression therapy in clinical trials.

Country of origin	Number of questionnaires analyzed (N=42)	Percentage of answers among all responding identified countries (N=40)
France	23	57.5%
Brazil	8	20%
Denmark	2	5%
Greece	1	2.5%
India	1	2.5%
Indonesia	1	2.5%
Malaysia	1	2.5%
Poland	2	5%
Switzerland	1	2.5%
Unknown	2	

Self-Reporting by Patients

The scoring of the level of trust by MD of the patient self-reporting adherence to the compression therapy in clinical trials on a 10 points scale (0 no trust- 10 full confidence) showed that 72.2% (26/36) scored above 5. Sixty nine percent of the 35 MD who responded to the question thought that the patient followed very well (3%) or rather well (66%) the instructions given in the clinical study protocols about the wearing of compression. Main comments to this question focused on the fact that if the protocol is well explained to the patient, he or she will follow it correctly.

Fifty-five percent (18/33) agree that « the current patient self-evaluation method is satisfying and precise enough to fulfil their needs". Sixty seven percent of the MD who disagreed stated that using self-reporting questionnaires cannot precisely reply to the question of the dose-effect of compression therapy.

Monitoring Device

The device was shortly presented in the survey in a figure (Figure 1). Concerning the availability of an adherence monitoring device that could be used in clinical trials, 88% (29/33) of responders would be interested to use it and 91% (30/33) found that it could improve the quality of the clinical trials The major results are summarized on Figure 2.

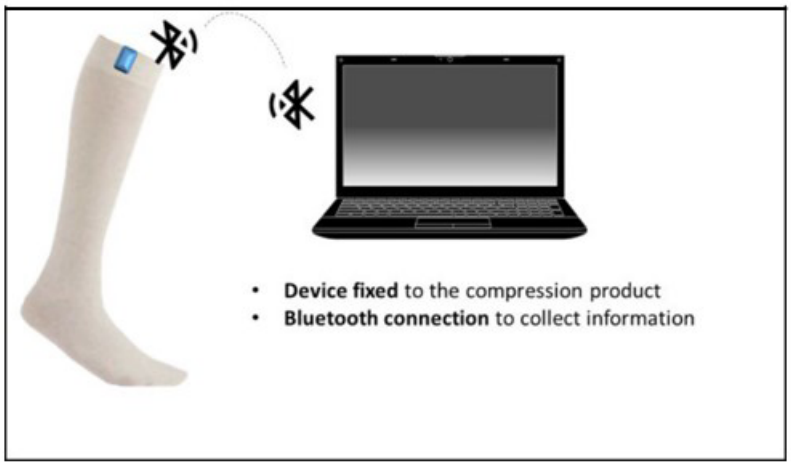

Figure1: Schematic representation of the new monitoring device dysplayed in the itnernational survey questionnaire about the need of devices in reporting the wearing time of compression therapy in clinical trials.

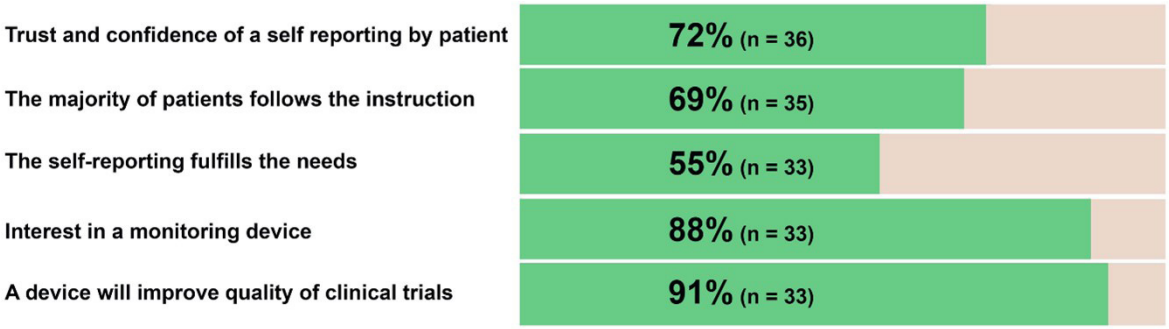

Figure 2: Summary of major responses to the survey. Green blocks are agreement in percentage of respondents to the summary of the question on the left. Number of respondents to each question are in parenthesis.

Device Features

Sixty-nine percent of MD (22/32) would be interested in knowing the number of washes made by the patient. The reasons explained in the comment boxes were that the responders believed there is a relationship between pressure loss and number of washings or modifications of fabric properties and washings.

Fifty percent (16/32) of responders wished that the device works three months and 28.8% (9/32) six months. For 41% (13/32) the device should measure every hour and for 28.8% (8/32) every 30 minutes.

The estimated price by the MD is varying from 10 USD per device to several hundred for the entire trial. It is expected to be low.

It is also expected by MD, that the pressure be recorded at different points in the leg using the same sensor. In the same way, measurement of resting and working pressures is desired. Il should also monitor how many times the compression stocking was applied and removed.

Discussion

The aim of this international survey was to know if opinion leaders on compression therapy would be interested in using a new monitoring device which is a sensor that sticks to the fabric, to objectively measure the compliance of compression therapy in clinical trials and if yes what would be the basic practical features of the device.

Forty-two opinion leaders on compression therapy responded to the survey. In order to get an idea of how large they were representative of the compression experts worldwide we can refer to the International Compression Club ordinary members (ICC). There are 390 listed members from 53 countries (https://www.icc-compressionclub.com : 22 of August 2022 query, excluding the members from manufacturers). Consequently the responses to the questionnaire represented 10.8% of the number of the ICC ordinary members. This figure could be considered as low considering that experts of compression therapy are not members of the ICC (Referring to the names of the first authors of the articles published on compression trials). Conversely, members of the ICC are perhaps researchers interested in compression but not experts since the results of the procedure of admission to the ICC is not public.

Nevertheless, in spite of the limitations above mentioned, this comparison provides an interesting indication of the scope of the survey: the comparison showed that the ratio respondents/ICC members country to country were 100% for France, 40% for Brazil, 25% for Switzerland and Denmark and 14% for Poland and India. As a consequence this survey is in majority a representation of French and Brazil experts opinions.

The major result of the survey is that 72.2% of respondents trust in the validity of a self-questionnaire to report compliance of compression therapy in clinical trials. Moreover, the survey highlights that majority of opinion leaders on compression therapy found that home-made self-questionnaires were reliable enough to report compliance to compression therapy and trusted in patient reporting if instructions were well explained to patients.

Validate a self-questionnaire to measure compliance to compression therapy using a thorough scientific method, before its use in trials, does not appear mandatory to investigators. It seems to be confirmed from major last published trials on compression therapy in which home-made questionnaire were used [14, 17]. In few trials, home-made questionnaires are based on questionnaires already used for drug trials, without limitations, and considered as reliable [17]. This behavior remains unexplained, nevertheless in these important trials on compression therapy, the first authors were not experts in compression. Expertise in that field is often delegated to manufacturers providing compression devices in the trials.

The results, if verified on a larger scale, could explain why sensors, which have already been developed [18, 20] and tested [12,13], are not used in the studies, nor is the validated questionnaire [11].

Nevertheless and surprisingly in spite of the above mentioned statements, the respondents find an interest in a new device (to replace the self-reporting method) even if they previously said that the self-questionnaire would do the work since 30 of the respondents would use the device when available.

The survey also shows that 88% of opinion leader were interested in the new device presented in the survey even if already existing sensors that sticks to the fabric to objectively measure the compliance of compression therapy in clinical trials are available. Moreover, they all go on to and fill the next question of the survey precising what would be the best features of such new device. This interest may be explained by the expectations of the respondent that not only the device record the compliance but also record the pressure in different points of the leg and more interestingly record the resting and working pressure. Two functions in one since pressure monitoring sensors have already been developed for fabrics [21, 22].

What every expert should know on pressure is that the pressure is variable at any (micro)point of the leg depending on the leg morphology (it is the reason why the interface pressure at any point cannot be used for compression pressure standardisation). Recording the pressure at different point of the leg will probably provide data that will be very difficult to interpret.

The number of washings is also one of the major features that is expected to get from the sensor. The number of washings performed by the patient is an interesting information to know: the more washings made, the better the stocking pressure is maintained. It is well known by the manufacturers that the pressure of the stocking decreases during the wearing due to the fatigue of the threads and is restored by an every-day washing.

Finally, recording the wearing time using monitoring sensors would more objectively answered to one of the major question in compression therapy : the dose-effect of compression in the different indications which is one of the goal expected by an expert consensus [23].

Conclusion

Although the survey shows that majority of respondents are satisfied with the use of self-administered questionnaires to measure compliance with compression in clinical studies, the use of sensors is seen as a way of improving the interpretation of results from clinical studies on compression more generally.

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Annex 1: Survey-questionnaire used for international on-line survey targeting opinion leaders on their need for a new device to measure compliance to compression therapy during clinical studies.

INTEREST FOR USING AN Adherence MONITORING DEVICE FOR CLINICAL STUDIES RELATED TO COMPRESSION

29/06/20

Context

SIGVARIS is currently working on an adherence monitoring related to clinical studies for compression products.

SIGVARIS is willing to receive feedback from the medical community. As an expert in these research fields, your participation to this study will be highly appreciated.

INTRO - Respondent profile

What country are you from?

☐ Austria

☐ France

☐ Germany

☐ India

☐ Italy

☐ Poland

☐ Switzerland

☐ UK

☐ USA

☐ Other :

How many studies have you conducted in your institution in the last 3 years?

Number of studies conducted in the last 3 years : _____

Part 1: State of the art of clinical trials involving medical compression

1. The standard method used to assess the patient adherence to medical compression is based on the self-declaration by the study participants

On a scale from 0 to 10, how would you rate your level of trust and confidence regarding the information collected using this methodology?

0 means no confidence at all, 10 means full confidence.

Note : _____ / 10

2. In which way do you think patients correctly follow the prescribed wearing protocols defined in clinical studies?

According to you, the majority of patients included follows the instructions…

☐ Very Well	☐ Rather Well	☐ Rather badly	☐ Very badly	☐ I don't know

Comments if any :

3. In which way do you agree to the following sentence: the current patient self-evaluation method is satisfying and precise enough to fulfill my needs.

☐ Fully agree	☐ Rather agree	☐ Rather not agree	☐ Not agree at all	☐ I don't know.

Comments:

(continue with question 4 if you disagree with questions 3, if you agree, go to part 2)

4. From your opinion, how much does the lack of an adequate adherence assessment method impact the quality of study results (more than one answer is possible):

☐ Results are not credible enough

☐ Lack of information regarding dose/effect relation

☐ Insufficient data accuracy to answer medical and scientific objectives

☐ An accurate documentation of hours and days of wearing compression is hardly possible

☐ Other, please explain:

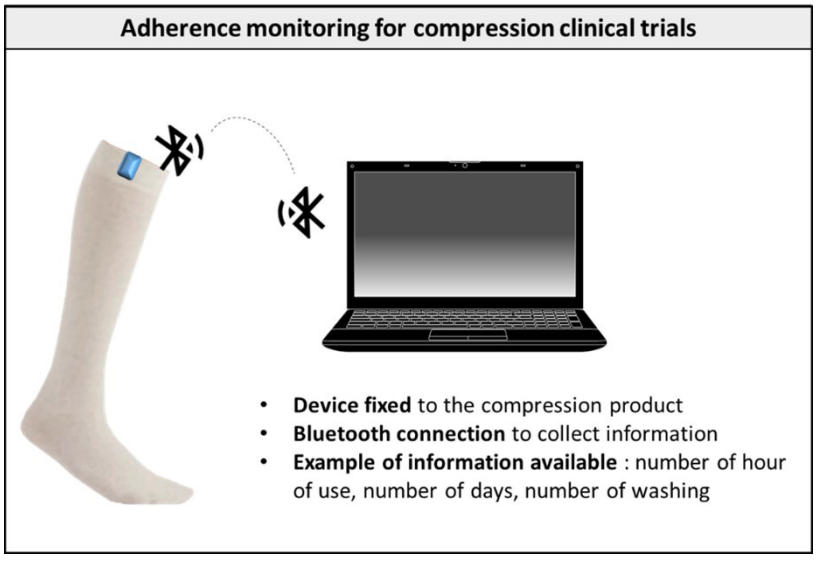
Comments :

Part 2 – Interest for an adherence monitoring device

SIGVARIS is currently working on an innovative project relative to adherence monitoring.

We would like to get feedback about your interest in using such a technology for further clinical trials.

This is how the monitoring device could look like :



5.If an adherence monitoring device would be developed and be available for use during clinical studies, replacing the self-declaration method, how interested would you be to use it?

☐ Very interesed	☐ Rather interested	☐ Rather not interested	☐ Not interested at all	☐ I don't know.

6.According to your opinion, how would such a device increase the quality of clinical studies?

☐ Definitevelly yes	☐ Rather yes	☐ Rather no → END QNR	☐ Not at all → END QNR	☐ I don't know → END QNR

7.What level of precision in terms of wearing time monitoring this device should have to be used during clinical studies? (several answers are possible)

☐ **Number of hours of use per day**

☐ **Number of days of USE** for the entire clinical research timeframe

☐ **Number of days of NO USE** for the entire clinical research timeframe

Comments:

Part 3 – Device features

Let's think about the technical requirements of this adherence monitoring device.

8.Would it be useful to monitor the number of washes made during the clinical studies?

Yes ☐	No ☐	.I don't know

Additional comments:

9.How long should the device work?

1 week

1 month

3 months

6 months

10.How many measurements should be possible per day?

Continuous measurements

Every 10 minutes

Every 30 minutes

Every hour

Every 2 hours

11.What price would be adequate for you?

Price per monitoring device : …….€

12.What would be the main characteristics to consider? Could you describe in simple terms the ideal adherence monitoring device you would use in a clinical study? What features would you include?

Main features:

13.SIGVARIS might work on monitoring devices prototypes in the upcoming months. Would you agree to be contacted again to give your opinion on it?

Yes ☐	No ☐

14.Would you recommend us to contact one of your peers to send him/ her this current questionnaire?

☐ Yes : email adress :	☐ No

This questionnaire is now completed. Thank you very much for your time