


Sizing of medical below-knee compression stockings in an Indian population: A major risk factor for non-compliance

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Abstract

Background: The compliance to compression stockings in India is poor. One of the reasons is related to the inadequacy of sizing tables of compression stockings sold in India by western companies.

Methods: In 922 Indian patients, three circumference measurements of leg were taken in a standing position at different levels: Instep (level Y), Ankle (level B) and largest part of the calf (level C). We compared these measurements with the standard sizing tables according to the recommendations of the manufacturers' sizing tables. The statistical analysis method: mean comparison of the circumferences was tested with the Wilcoxon test.

Result: The measurements found do not allow a satisfactory adaptation of compression stockings marketed in India by Medi[®], Sigvaris[®] and Jobst[®]. The risk of threading difficulties is 15% with Medi[®] and Sigvaris[®] compression stockings. The risk of slippage is 61% for Sigvaris[®] and 48% for Medi[®]. With the Jobst[®] sizing table, no knitting makes it possible to reach a pressure at point C equal to at least 50% of the pressure of point B.

Conclusion: These data underline the need to adapt the measurements of compression stockings to the morphologies of patients' lower limbs in India, to improve compliance.

Keywords

Compression stockings, compliance, leg measurements

Background

Compression stockings are the major long-term treatment of acute, chronic venous and lymphatic disorders recommended by International consensus. However, there is a lack of data concerning the real patient compliance to treatment. Few publications have underlined the poor observance of wearing medical stockings.^{1–4} Several main reasons are reported:

- Inefficiency;
- Compression stockings too rarely prescribed by a physician;
- Not very well accepted during the early stages of chronic venous disorders;
- High cost;
- Poor tolerance

On the other hand, in Indian patients (North India), morphology of the lower limbs is very different from

that of the European patients. This could be an explanation for the inefficacy and poor compliance of CS in the Indian population.

The objectives of this study were to measure the legs of 922 Indian patients originating from Punjab (North India) and to compare these measurements with the standards sizing tables of Medi[®] Bayreuth, Sigvaris[®] and Jobst[®] compression stockings (CS).

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Materials and methods

Study

This is a single-center data collection. We achieved an epidemiological study of sampling of leg measurements in a population of Punjab (India).

Patients

Information was given to all selected patients. This study was realized in accordance with the Declaration of Helsinki of WMA between 1 April 2017 and 30 April 2017. Each patient was measured in either the left leg or the right leg. The choice of legs (right vs. left) measured was done using a list randomizer (<http://www.random.org/lists/>).

Description of the population at the inclusion (Table 1)

Inclusion criteria.

- Unselected patients of both sexes with undefined pathology seen in the vascular department of Fortis hospital (Mohali, Punjab) in April 2017.

Exclusion criteria.

- Patients under 18 years old
- Pregnant women
- Patients unable to stay in standing position for leg measurements.

Parameters assessed during this study

Three circumference measurements of leg were taken in a standing position (Figure 1):

We measured the circumferences at different levels according to the recommendations of the manufacturers' sizing tables to determine the size of the

below-knee CS. (Medi[®] (medi GmbH& Co. KG Medicusstraße 1, 95448 Bayreuth, Germany), Sigvaris[®] (Gröblistrasse 8, 9000 St. Gallen, Switzerland) and Jobst[®] (BSN-JOBST GmbH, Beiersdorfstraße 1, 46446 Emmerich am Rhein, Germany))

- Instep (level Y) only for medi-Bayreuth[®] and Sigvaris[®];
- Ankle (level B) for medi-Bayreuth[®], Sigvaris[®], and Jobst[®];
- Largest part of the calf (level C) for medi-Bayreuth[®], Sigvaris[®], and Jobst[®].
- Only these International brands are available in the Indian market.

We compared these measurements with the standard sizing tables available from Medi[®]-Bayreuth (Table 2), Sigvaris[®], (Table 3) and Jobst[®] (Table 4).

What were our comparison criteria?

1. *Regarding the difficulties of donning:* if the instep (Y) of the patient on the sizing table is bigger than the maximum ankle measurement (B), we can consider that the stocking is maladjusted.

For example, if we take Table 2, if Y is more than 31 cm, B is equal to 20 cm. The difference between Y and B will be more than 11 cm according to the table.

Therefore, we have considered that the maximum of Y minus the maximum of B is the limit acceptable for donning. In fact, this could be responsible for painful deep folds of the stockings on the instep, and so, can be a reason for non-compliance.

This value (maxY–maxB) which is different according to each size is displayed on the last line of the tables (Tables 2 and 3).

Table 1. Description of the population (922 patients).

	Males	Females	Total
Sex, n (%)	604 (65.5)	318 (34.5)	922 (100)
Age ^a (years)	54.0 (15.7)	50.3 (17.7)	52.7 (16.5)
Weight ^a (kg)	71.9 (13.2)	67.8 (12.5)	70.5 (13.1)
Size ^a (cm)	172.2 (4.8)	163.7 (8.0)	169.2 (7.3)
BMI ^a	24.3 (4.5)	25.6 (8.0)	24.7 (5.9)
Measurements			
Y ^a (cm)	31.6 (3.0)	30.4 (2.4)	31.2 (2.9)
B ^a (cm)	22.4 (2.2)	21.8 (2.6)	22.2 (2.4)
C ^a (cm)	31.9 (4.8)	31.9 (4.6)	31.9 (4.7)
Chaussage			
Flip flop (%)	91	89	89.5

^aMean (standard deviation).

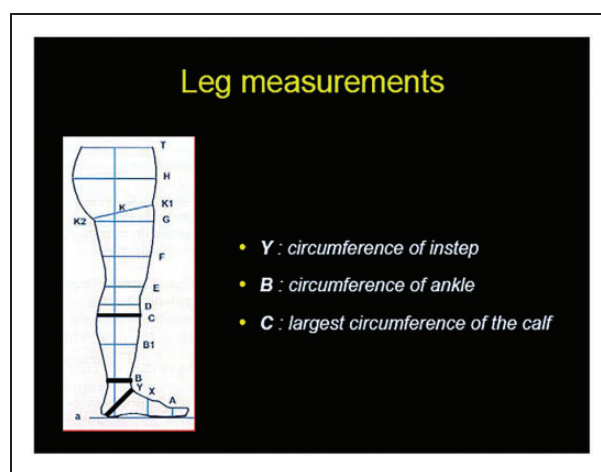


Figure 1. Leg measurements.

Table 2. Sizing table of Medi[®] (medi Active[®], mediven Comfort[®], mediven Plus[®]).

Circumferences (cm)	I	II	III	IV	V	VI	VII
C	28–34	30–37	33–40	35–43	37–46	39–49	41–51
B	18–20	21–22	23–24	25–26	27–28	29–30	31–32
Y	26–31	28–33	29–35	31–37	32–38	33–40	34–42
minC–maxB	8	8	9	9	9	9	9
maxY–maxB	II	II	II	II	IO	IO	IO

Note: The bold values indicate the value of minC-maxB and maxY-maxB of each sizing column.

Table 3. Sizing table of Sigvaris[®] (Cotton Class II).

Circumferences (cm)	X small	X small+	Small	Small+	Medium	Medium+	Large	Large+
C	29–36	33–40	33–40	35–42	35–42	38–45	38–45	42–49
B	20–22	20–22	22–24	22–24	24–26	24–26	26–29	26–29
Y	28–33	28–33	29–35	29–35	31–37	31–37	32–38	32–38
minC–maxB	7	II	9	II	9	12	9	13
maxY–maxB	II	II	II	II	II	II	9	9

Note: The bold values indicate the value of minC-maxB and maxY-maxB of each sizing column.

Table 4. Sizing table of Jobst[®].

Circumferences (cm)	S	M	L	XL	LFC	XLFC
C	28–38	30–42	32–46	34–50	46–61	46–61
B	18–21	21–25	25–29	29–33	25–30	30–36
C–B	7	5	3	I	16	10

Note: The bold values indicate the value of minC-maxB and maxY-maxB of each sizing column.

2. *Regarding the difficulties of slippage:* if the minimum calf circumference (C) of the patient on the sizing table is smaller than the maximum ankle measurement (B), we can consider that the stocking is mal-adjusted, and there is a risk of slippage.

For example, if we take the Table 2, if C is less than 29 cm, B is equal to 22 cm. The difference between C and B will be less than 7 cm according to the table. This could be responsible for slippage, and so, be a reason for non-compliance.

This value (minC-maxB), which could be different according to the sizing class, is displayed on the penultimate line of Tables 2 and 3.

Finally, our criteria for non-adaptation of the stockings were: maxY-maxB should be strictly superior to the table values and minC-maxB should be strictly inferior to the table values.

Statistical methods

The statistical analysis was performed with JMP software (version 12 pro for Mac). The mean comparison of the circumferences was tested with the Wilcoxon test with a $p < 0.05$ considered as significant.

Table 5. Leg measurements according to sex.

Size (cm)	Males		Females		p ^a
	Mean	sd	Mean	sd	
Y	31.2	4.1	29.6	3.7	<.0001
B	22.4	2.2	21.8	2.6	<.0003
C	31.8	5	31.9	4.6	NS

^aTest of Wilcoxon.

Results

The distribution of measurements is different between the both sexes among the studied population (Table 5). We can see that the Y–B value is significantly bigger among the male, with a higher difficulty of donning. The male's C–B value is also smaller, with a higher risk of slippage.

If we rely solely on the averages of the measurements, we find that the measurements of the subjects studied correspond to the sizes proposed by the manufacturers.

But regarding the repartition of the C–B value (risk of slippage), it is not the same for the sizing tables of Medi[®] and Sigvaris[®]. The risk of slippage (Figure 2) is much higher and significantly different between the two



Figure 2. Examples of slippage of compression stockings in Indian male patients.

Table 6. Results for difficulties of donning and risk of slippage.

	Male (%)	Female (%)	Total (%)
Medi [®]			
C–B slippage ^a	51	42	48
Y–B donning	18	9	15
Slippage or donning	64	49	59
Sigvaris [®]			
C–B slippage ^a	63	57	61
Y–B donning	18	9	15
Slippage or donning	72	61	68

^aComparison of Chi² slippage, $p < .0001$

brands in the global population and by sex: respectively 48% for Medi[®] and 61% for Sigvaris[®] ($p < .001$) (Table 6).

Discussion

We calculated the risk of slippage and difficulties of donning the CS, size by size, brand by brand, sex by sex and we decided to present only the global results in order to simplify.

In this study, we compared the measurements of anatomical points on the legs with the standardized points of the manufacturers, but we did not measure the length of the legs. This could be an additional risk of slippage, which was not taken into account here.

The risk of slippage is associated with a risk of insufficient pressure at point C. Usually, the recommended pressure level at point C⁵ should be between 80% and 50% of the pressure at point B. If the pressure at point C is too low, the CS will not be efficient.

For this reason, we did not use Jobst[®] sizing table in our study. With such a sizing table, no knitting makes it possible to reach a pressure at point C equal to at least 50% of the pressure of point B. The clinical efficacy of those stockings seemed questionable to us.

We only studied 922 healthy subjects and this sample is not representative of Punjab population (estimation 30.4 million in 2018 with 850 females for 1000 males). This is only an ethnic sample characterizing morphologic shape of the leg and the foot (Figure 3) in Punjab.

The volume of the leg increases throughout the day. If the measurements are taken in the evening, the stockings may slip during the morning due to less swelling in subjects whose B–C is lower than the values proposed by the manufacturer.

It appears from these results that compression stockings sold in India (Punjab) are not adapted to the leg morphology of the Indian patients. These stockings correspond to morphologies of European legs. These differences may explain, apart from the great climatic differences, the poor compliance of stockings in India.

The same problem arises in other countries (e.g. China). Rong Liu et al.⁶ underlined this problem and proposed a novel methodology to categorize lower

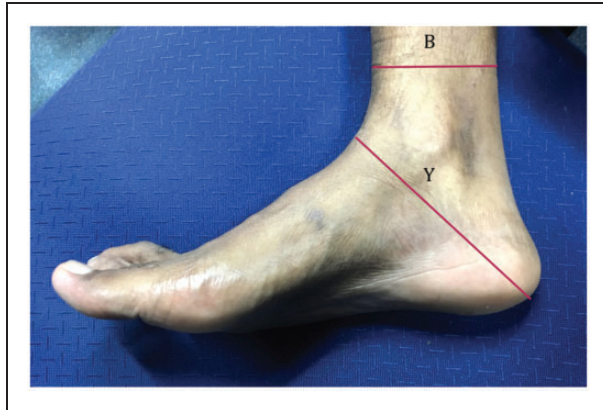


Figure 3. Example of an Indian foot.

body shapes and sizes with the use of a three-dimensional digital anthropometric technology to improve the fitting, hence the compliance.

Conclusion

In this study, we measured the legs of 922 Indian patients and compared these measurements with the sizing tables of Medi® and Sigvaris® compression stockings. We found that the measurements of the legs of the patients may be the cause of difficulties of putting on the stockings in 15% of the patients. The Medi® sizing table is not suitable in 48% of patients and Sigvaris® sizing table in 61% (risk of slippage).

These data highlight the need to adapt the measurements of compression stockings to the morphologies of patients' lower limbs in each country where manufacturers want to set up.

Declaration of Conflicting Interests

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Ethical approval

Not applicable.

Contributorship

Conception and design: JFU and JPB. Analysis and interpretation JFU and JPB. Data collection RJ. Writing: JFU; Critical revision: JFU. Final approval: JFU and JPB. Statistics: JFU. Overall responsibility: JFU.

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