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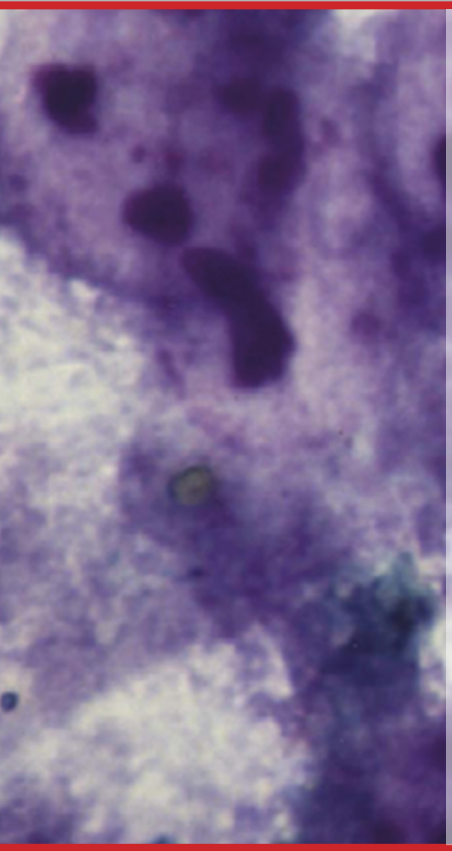

Offprint

Tamia – a new type of vibrating tampon for the treatment of period pain

Practice experience report

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Tamia – a new type of vibrating tampon for the treatment of period pain

A practice experience report from Swiss gynaecologists practising in medical office treating primary dysmenorrhoea

A new method based on a low-frequency vibration treatment proves to be effective against the painful symptoms suffered in primary dysmenorrhoea. In a clinical study, the pain-relieving tampon Tamia® (Vipon AG) proved to be at least as effective as ibuprofen. One application of 60 minutes per cycle is usually sufficient.

Johannes Bitzer, Suzanne Aebi, Regina Widmer, Pierre Villars

Over 80% of adolescent women in Switzerland suffer at least from individual symptoms of dysmenorrhoea (1), and almost one in two women is regularly affected by cramps in the uterus and other painful symptoms during menstruation (2, 3). Particularly frequent symptoms are abdominal and back pain; other typical symptoms are nausea, aching limbs and headaches.

With dysmenorrhoea, a distinction is made between secondary dysmenorrhoea, which is a symptom of an underlying medical condition (e.g. endometriosis), and primary dysmenorrhoea, where no other condition causes the pains. The symptoms of primary dysmenorrhoea begin either shortly before or at the latest at the start of each menstrual bleeding (2).

The release of endometrium prostaglandins (PG) plays an important role in the onset of menstrual pain. Thus, women with primary dysmenorrhoea have increased levels of PG. It is known that the pain mediators in the uterus are responsible for both the relaxation as well as the contraction of the muscles, depending on the physiological situation. The PG-mediated contractions in the area of the uterus in particular can be very painful during the shedding of the uterine lining (4, 5).

Therefore nonsteroidal anti-inflammatory drugs (NSAIDs) such as ibuprofen and low-dose contraceptives are usually used for the treatment of primary dysmenorrhoea (6–10).

A vibrating tampon as new method of treatment

The vibrating tampon Tamia® (www.tamia.com) is based upon a completely new approach. This tampon is equipped with a small engine producing a gentle, low-frequency vibration in the area affected by the pain, which has an antispasmodic and pain-relieving effect.

Once menstrual pain or cramps begin, the Tamia tampon, with its outer layer made of viscose, is inserted into the vagina and placed like a conventional tampon. Correct positioning is reached, once the tampon can no longer be felt. The vibration treatment is initiated by pressing the switch on button at the end of a wire and it lasts for one hour, after which the vibration will automatically stop and Tamia can be disposed of. One single Tamia tampon per menstruation is sufficient for the vast majority of women to treat the symptoms.

Models to explain the effectiveness

Two mechanisms are currently discussed as possible explanations for the effectiveness of Tamia. According to a first hypothesis, the vibration of the tampon may have an effect on the nerve pathways, thus attenuating the transmission of pain signals to the brain. In doing so, according to the gate-control hypothesis, inhibitory neurons in the spinal cord should be activated in much the same way as the muscles are stimulated with the TENS method (transcutaneous electrical nerve stimulation), which is already used in various other pain syndromes, including dysmenorrhoea (11–14).

The second hypothesis is based on the fact that the gentle vibration of the Tamia tampon stimulates the muscles of the uterus and the cervix uteri and improves blood flow. This could influence the synthesis and release of PG in the menstrual fluid, thus altering the concentration equilibrium between the different forms of PG. This mechanism could modify the physiological effect from the contraction to the relaxation of the uterus. Information concerning the importance of a modified PG pattern can be found in literature on the pharmacotherapy of menstrual pain focusing on prostaglandin (15, 16).

Studies conducted

To confirm the effectiveness and safety of this new method of treatment, a clinical study was carried out at two clinics in Kansas, Missouri/USA, between 2006 and 2010 (17). The double-crossover study of 115 patients and a total of 383 cycles (Tamia: 191, ibuprofen: 192) based on a non-inferiority approach found that the vibrating tampon is at least as effective against menstrual pain as ibuprofen. There is no evidence of any irritations caused by the vibration or other side effects caused by the tampon (17). Another clinical comparative study of phase III has been running with 81 patients at the University Women's Hospital in Basel since November 2011, comparing Tamia and 400 mg of ibuprofen.

Objective of the practice experience report

This report examines the effectiveness of the vibrating tampon Tamia in everyday conditions, and provides an insight into its acceptance among users in Switzerland.

Method

8 gynaecologists from German-speaking Switzerland and a total of 50 patients

took part in the practice experience report (PER) to test the vibrating tampon Tamia. The criterion for being included in the PER was a diagnosed primary dysmenorrhoea without concomitant medical conditions. The treatment and collection of data took place in the period from November 2011 to May 2012.

All the patients received two tampons and two extensive, formally structured questionnaires. The first tampon was to be used during the first cycle, the second tampon was to be applied either during the same cycle or during the following cycle. Each tampon could only be used once. The symptoms before the treatment and the pain relief after the application were documented in the two questionnaires: «First use» and «Second use». The patients were asked to rate the intensity of the pain before and after the application on a modified numeric Melzack-McGill scale from 0 (no pain) to 10 (very severe pain) (18). Concomitant symptoms (cramps, pain in the stomach, bowels, lower back/lumbar area, head or other) were respectively divided into 4 levels of intensity (0 = none, 1 = mild, 2 = moderate, 3 = severe).

The patients had the option of taking additional medication or using an alternative method to relieve their symptoms. In addition, questions were asked regarding treatment satisfaction, as well as wearing comfort and potential application problems or unpleasant sensations.

The pooled data was analysed using the statistical package R (R Foundation for Statistical Computing, Vienna, Austria; www.R-project.org, version 2.14.1 for Mac OSX).

Tests for significance when comparing the different scales between the two measurement time points were carried out using the «Wilcoxon matched-pairs signed ranks test». The Spearman's Rho was calculated for the correlation between the variables, and the significance level was set at 5%.

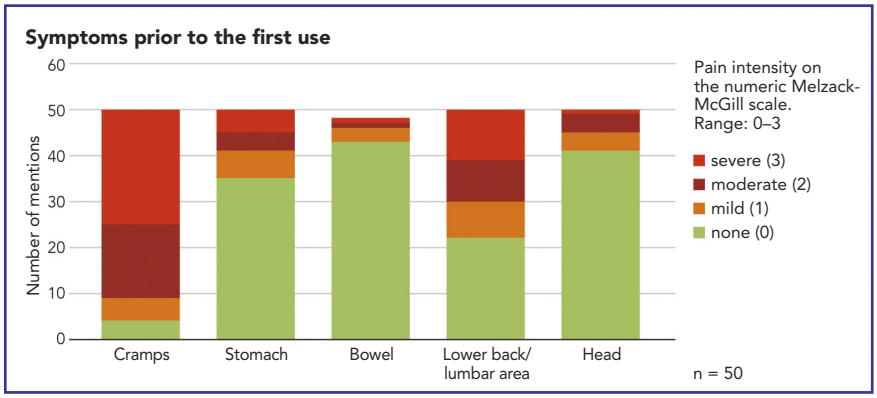

Figure 1: Symptoms prior to the first use of Tamia

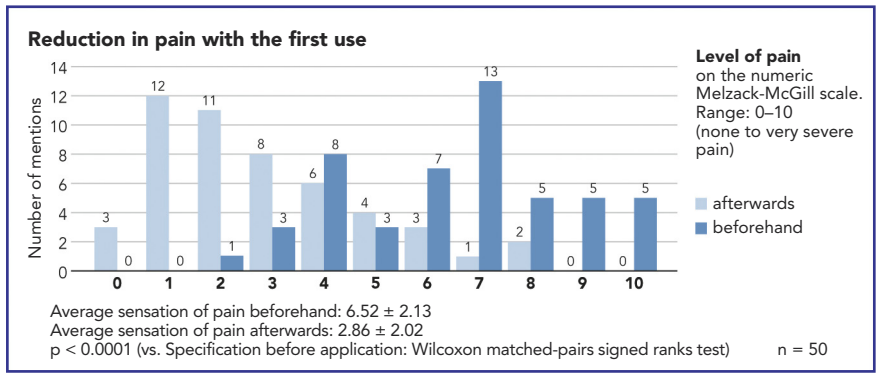

Figure 2: Pain before and after the first use of Tamia

Results

General information

The «First use» questionnaire was completed by 50 women suffering from dysmenorrhoea, aged between 16 and 47 years (average age 28.8 ± 8.6 years). Around 46% of the patients were in the age group of 21–30 years, 28% in the group of 31–50 years. 64% of these patients (32 out of 50) decided to continue with the second application of the vibrating tampon either during the same or the next menstrual cycle. The average age was 28.9 (± 9.0) years (16–47 years).

Discomfort before use

The most prevalent pain of the participants in the PER (n = 50) prior to the first use was indicated on the numeric Melzack-McGill scale (MMS) with an average of 6.52 (± 2.13; the range being 2–10: mild pain to very severe pain).

The menstrual pain that already existed at the beginning (or before the first application) was mainly felt as cramps, pain in the lower back/lumbar area as well as stomach symptoms (*Figure 1*).

Results after the first use

The before-and-after comparison of the pain intensity after the first use of Tamia shows a substantial change in the distribution of the intensity from the right half of the scale (severe pain) to the left (low pain/no pain) (*Figure 2*). The average pain was significantly reduced in statistical terms by -3.66 (± 2.15) points (p = 0.014, *Table 1*) due to the vibration therapy. Three patients claimed to be completely free from pain after the vibration treatment. Over 70% of patients (n = 35) experienced a reduction in pain within 45 minutes or less. After the initial application of the vibration therapy, 52% of the patients were able to do without additional means or an additional method to relieve pain. After using the Tamia tampon, 18 patients took a painkiller, one woman during the treatment already. 5 women reported using a treatment that did not involve medication. The additional use of pain relievers was on average 5.4 (± 4.1) hours after using Tamia (range: 0.5 to 24 hours). The overall satisfaction of the patients with the tampon was 74%.

Results after the second use in the same cycle

Of the 32 patients who tested two vibrating tampons in the context of the PER, 8 women used the second tampon in the same cycle, meaning that 25% of the pa-

Table 1: Reduction of menstrual discomfort with dysmenorrhoea by using the vibrating tampon Tamia: First and second use in the same and the following cycle.

	First use n = 50		Second use, same cycle n = 8		Second use, following cycle n = 24	
Pain intensity before treatment	6.52 ± 2.13	n = 50	6.13 ± 1.64	n = 8	6.04 ± 2.54	n = 24
Pain intensity after treatment (deepest point of pain)	2.86 ± 2.02	n = 50	2.75 ± 2.38	n = 8	2.24 ± 1.98	n = 24
Pain reduction absolute	-3.66 ± 2.15 p < 0.0001 (vs. before use; Wilcoxon matched-pairs signed ranks test)	n = 50	-3.38 ± 2.07 p = 0.014 (vs. value before second use; Wilcoxon matched-pairs signed ranks test)	n = 8	-3.63 ± 2.62 p < 0.0001 (vs. value before second use; Wilcoxon matched-pairs signed ranks test)	n = 24
Speed of the pain relief (cumulative)						
First felt in ≤ 30 minutes	46%	n = 23	37.5%	n = 3	37.5%	n = 9
First felt in ≤ 45 minutes	70%	n = 35	80%	n = 6	67%	n = 16
Proportion of patients without additional medication	52%	n = 26	75%	n = 8	71%	n = 17
No direct pain after treatment	40%	n = 20	38%	n = 3	25%	n = 6
proportion of test women that are asymptomatic > 8 h	40%	n = 8	33%	n = 1	50%	n = 3
Direct pain despite treatment	60%	n = 30	62%	n = 5	75%	n = 18

Type and frequency:	strong	moderate	mild	none	strong	moderate	mild	none	strong	moderate	mild	none
- Cramps	10%	40%	33%	17%	–	40%	60%		–	28%	39%	33%
- Stomach	–	3%	10%	87%	–	–		100%	–	–	17%	83%
- Bowel	–	7%	10%	83%	–	–	20%	80%	–	–	11%	89%
- Lower back/lumbar area	3%	17%	27%	53%	20%	20%	40%	20%	6%	22%	33%	39%
- Head	–	7%	3%	90%			20%	80%	11%	–	17%	72%

tients (n = 32) decided to extend the vibration therapy during the first cycle.

The initial pain intensity before the second use of the vibrating tampon was 6.13 (± 1.64), slightly lower than before the first use (*Table 1*). The average pain relief before compared with after the second application in the same cycle was -3.38 (± 2.07), which was significant (p = 0.014; *Table 1*). Approximately 38% (n = 3) of the patients no longer had any symptoms after having used the tampon twice (*Table 1*). 75% of the patients reported being satisfied with the treatment using the vibrating tampon.

Results after the second use in the following cycle

24 out of the 32 patients (75%) used the second vibrating tampon in the following menstrual cycle. The average pain reduction compared to the pain level before the second application in this case was -3.63 (± 2.65) points (p < 0.0001). The proportion of patients who used Tamia without needing further medication to relieve symptoms amounted to 71% after the second use in the following cycle. 7 patients (29%) waited an average of 3.8 (± 3.6) hours after applying Tamia before taking any pain relievers (*Table 1*). Around 66% of the patients who used Tamia for the second time in the following cycle rated it as being either equally effective or more effective than their previous treatments. 71% of the patients appeared to be satisfied or very satisfied with Tamia.

Evaluation of the vibration and wearing comfort

74% of the patients (37 out of 50) stated that they would recommend Tamia to a friend or their daughter after having used it for the first time. 52% of the patients described the vibration as being comfortable, 18% as uncomfortable, and 30% as neutral. 74% described the wearing comfort (or the wadding) as very comfortable or comfortable.

Discussion

This PER investigated the effectiveness, practicality and acceptability of a new type of treatment for painful symptoms in primary dysmenorrhoea. By using the vibrating tampon Tamia both the first and the second time in the following cycle, a highly significant reduction in pain of approximately -3.6 points was attained on the numeric MMS scale (p < 0.0001).

The pain relieving effect of Tamia was felt within a maximum of 45 minutes by over two thirds of the patients, regardless of whether the vibrating tampon was used for the first or the second time. Approximately 38% of the patients experienced an onset of the effect within 30 minutes or less during their second use. This quick reduction in pain was also evident in the pivotal study conducted in Kansas, USA, which compared the vibrating tampon with ibuprofen (17). In the double-crossover study, Tamia reduced pain within the first hour (i.e. after 15, 30 and 60 minutes) with a significant difference: Not only was it better, but it also acted faster than ibuprofen. In the non-inferiority study, Tamia was found to be at least as effective as the standard therapy of ibuprofen (17).

In the present analysis, no plausible explanation can be found for the results showing that the proportion of patients experiencing complete pain relief after the first and second use in the same cycle was 40%, or 38%, while only 25% of the patients were completely pain free after the second use in the following cycle. The latter value, however, concurs with the data of the above-mentioned

study in Kansas, where patients were completely pain free (score = 0 on the MMS scale) after two hours in, on average, 23.6% of all cycles treated with the vibrating tampon (45 of 191) (17). 31.9% of the cycles in this study were almost without pain (score = 1–2) two hours after having applied the vibration therapy. Therefore, on a cumulative basis, over half (56%) of the cycles proved to be pain free or at least almost pain free, due to the vibration therapy.

In this analysis, 66% of all the women (both during the first and second use) perceived Tamia as being better than or at least as effective as their previous methods. 75% of the patients were able to successfully treat their symptoms with just one tampon per menstruation. The patients were generally satisfied or very satisfied with the vibrating tampon. The majority stated that it would positively influence their quality of life. Tamia was assessed by most patients as being comfortable and easy to use. The open-ended questions revealed that a reduced use of or abstention from painkillers was the most important advantage of the product for many of the women. A large majority of the patients would recommend the special tampon to a friend or daughter.

The PER shows the known limitations regarding scientific evidence. The women enrolled in the study were motivated; they were interested in an alternative treatment and were selected by their gynaecologists. This means limited external validity of the results. At the same time the study was not designed for comparison (no placebo vs. comparator).

Conclusion

The results of this PER concur with the existing clinical data, both in terms of the intensity as well as the speed in which pain and cramps and other menstrual symptoms were reduced. The experience of the majority of the dysmenorrhoea patients interviewed shows that in everyday conditions, Tamia is a safe, easy-to-use as well as effective therapy with a high level of acceptance. Taking into account the limitations of an uncontrolled PER, the results of the investigation show that the pain-relieving tampon Tamia is a new treatment option for patients who suffer from dysmenorrhoeal discomfort. ■

Prof. Dr. med. Johannes Bitzer
(Contact address)
Frauenklinik des Universitätsspitals Basel
Abteilung für Gynäkologische Sozialmedizin und Psychosomatik
Universitätsspital Basel
4031 Basel
E-Mail: jbitzer@uhbs.ch

Dr. med. Suzanne Aebi
Aeschenvorstadt 21
4051 Basel

Dr. med. Regina Widmer
Theatergasse 26
4500 Solothurn

Dr. med. Pierre Villars
Dufourstrasse 143
8008 Zürich

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Interests:
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