Self-Administration of Medicines and Dietary Supplements Among Female Amateur Runners: A Cross-Sectional Analysis

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ABSTRACT

Introduction: Self-administration of medicines or dietary supplements without any physician’s advice is a widespread behavior and appears to be more frequently practiced by women. Moreover, reasons to self-administer products are often pains and injuries especially among athletes who might also use remedies to improve physical performance. The objective of this study was thus to assess the prevalence of self-administration of medicines and dietary supplements as well as its determinants among female amateur runners.

Methods: Our sample was comprised of women who took part in amateur running events. Data regarding self-administration of substances, exclusively aiming at being physically prepared for the running event (i.e., intake the week before), were collected through an anonymous self-administered questionnaire including four specific themes (i.e., general information, self-administered medicines and dietary supplements, context of self-administration of substances and knowledge of the anti-doping regulations).

Results: A total of 136 women, with a median age of 39 years (interquartile range: 27–47), volunteered. Among them, 34.6% reported self-administration of medicines during the period immediately preceding the running event, with the aim to be physically prepared. Moreover, 33.8% also declared self-administration of dietary supplements. Furthermore, we observed that about 8.1% of the sample had consumed a potentially doping substance. After adjustments for confounding

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variables, the probability of self-administration of products (medicines or supplements) increased significantly with the intensity of the activity and the membership in a sports club.

Conclusions: Our study showed that self-administration of products among female runners seems to be a widespread behavior, where the intensity of the sports practice and the network of runners seem to influence the decision to resort to this behavior.

Keywords: Amateurs sports; Dietary supplements; Female runners; Self-administration of products; Self-medication; Vitamin and mineral supplements

INTRODUCTION

Self-administration of products for their presumed health benefits and without any medical supervision is a current behavior and represents a public health concern. Self-administration of vitamin or mineral supplements is indeed a widely practiced behavior. Moreover, many individuals also resort to self-medication (i.e., self-administration of medicines). Although no consensus on a universal definition exists, self-administration of drugs involves consumption, without any health professionals' advice, of over-the-counter drugs but also of formerly prescribed medicines [1, 2].

While an appropriate self-administration of these remedies can provide some benefit (e.g., patient empowerment, reduction of health expenditure by government) [3], a non-responsible use can lead to serious health hazards [6, 8] (e.g., misuse, wrong dosage, adverse health events or interactions). The results of three recent studies [4–6] demonstrated that self-administration of substances is more prevalent among women probably because they seem more willing than men to recognize and voice the symptoms of health ailments [7].

Especially among amateur athletes, self-administration of medicines or supplements is undertaken for various reasons. Primarily, they are frequently exposed to pain, tiredness, injuries and difficulties with recovery and therefore decide to resort to self-administration of various products. They can also deliberately use dietary supplements and medicines in order to enhance their physical appearance and performance [9]. Moreover, because remedies usually self-administered in order to treat common health problems may contain substances prohibited by the World Anti-Doping Code [10], their consumption exposes amateur athletes to inadvertent doping [11], which could lead to unexpected penalties, although these controls seem uncommon in the amateur sports community.

Unfortunately, only limited epidemiological data on self-administration of products by amateur athletes exist. The few existing studies mainly focus on one particular product (i.e., only analgesics or only over-the-counter drugs) [12, 13]. These surveys observed a high prevalence of this behavior but did not distinguish self-administration of substances as a lifestyle habit from self-administration of substances at shorter term, with the aim to be physically prepared for a sporting event (i.e., during the period immediately preceding competition). Therefore, the objective of the current survey was to identify the prevalence of self-administration of products in the amateur sports population who aim at being physically prepared for specific sports events. We focused especially on female amateur runners because of
the still growing interest in this sport, especially among women, and their propensity to self-administer drugs or supplements more than men [5]. Moreover, too sparse information is available on the use of supplements and medicines in this population.

METHODS

Participants

Our sample consisted of female volunteers who participated in any of eight amateur running events of 10 or 21 km in the Province of Liège, Belgium, between August 2014 and March 2015. The different races were targeted on the basis of our geographic and availability constraints. There were no specific selection criteria except that women had to be aged 18 years or more. All women gave their written informed consent. This study received the approval of the Ethics Committee of the University Teaching Hospital of Liège under the reference 2014-173. All procedures followed were in accordance with the ethical standards of the responsible committee on human experimentation (Ethics Committee of the University Teaching Hospital of Liège, Belgium) and with the Helsinki Declaration of 1964, as revised in 2013. Informed consent was obtained from all patients for being included in the study.

Parameters Investigated

Data were collected through an anonymous self-administered questionnaire, specially developed to gather information regarding products that were self-administered by female runners. Our questionnaire consisted of 24, mainly closed, questions grouped into four main themes: general information, self-administered products, context of self-administration of substances and knowledge of the anti-doping regulations.

General Information

The questionnaire gathered self-reported socio-demographic and anthropometric data. It also asked about potential current illnesses. The level and intensity of usual sports practice (i.e., casual, amateur or professional, number of activities and number of hours of sports practice) were recorded. Women also had to indicate the length of the race chosen on that specific day (10 or 21 km) and whether they were a member of a sports club.

Self-Administered Products

Female runners were also asked to list all self-administered products they had consumed with the aim of being physically prepared for the competition. With the consumption of vitamins and food supplements lasting generally for a longer period than a drug, we decided to establish two different thresholds: within the last week for dietary supplements and maximum last 24 h for medicines. The following questions were asked to determine whether women resorted to self-administration or not: (1) “In order to be physically prepared for this specific running event, have you consumed vitamins and/or dietary supplements during the last week, without a doctor’s advice?”. (2) “Over the past 24 h, during your physical preparation for this event, have you taken medicines fighting against cough/asthma/sore throat/headache/fever/blocked nose/pains/stress/difficulty sleeping/decreasing performance/other?” By listing the various ailments against which athletes were likely to fight by taking medicines, it allowed us to
determine the reasons for this self-medication. We also inserted control variables to verify whether medicines were consumed with or without any physician advice (and then, self-administered) by asking the following questions: “Were these medicines prescribed by a doctor?” “If the medicine has been prescribed by a doctor, was it in order to be physically prepared for this running event?” Female runners were also requested to indicate the name of every single product in order to enable us to assess whether they were part of the prohibited list of the World Anti-Doping Agency.

Context of Self-Administration of Substances
We identified on which person’s advice, if any, subjects of our sample consumed products (e.g., familial acquaintances, sports acquaintances, colleagues), where products were acquired (e.g., family medicine chest, from friends and peers, at the pharmacy) and reasons to resort to self-administration of these remedies (e.g., lack of time, lack of financial means, symptoms that did not require medical consultation). For each of the questions enquiring about these, a list of pre-established answers was proposed. However, subjects had the opportunity to mention a response not listed. Respondents could report several sources and reasons.

Knowledge of the Anti-Doping Regulations
We enquired about knowledge of doping test regulations and of the World Anti-Doping Agency prohibited list. These four consecutive questions were asked: “Do you know that an official list of products, considered as doping, prohibited in sports currently exists?” “Before taking medicines, do you check if they figure on this prohibited list?” “Do you know at which level of competition you can be controlled and tested? If yes, specify the level.” “Do you think you could be controlled out of competition?”

Data Collection Tool
Our questionnaire was created in collaboration with experts in sports medicine, but also with experts in survey methodology. It was pre-tested in a sample of ten amateur athletes. We also performed a post hoc reliability analysis using a “test-retest” approach: 21 amateur athletes responded to identical questions at two different times but in an equivalent context. A time interval of 15 days was chosen. To determine the test-retest reliability, the intraclass correlation coefficient (ICC) was calculated for each item, constituting the four main parts: general information, products consumed, context of self-administration of products and knowledge of the anti-doping regulations. In summary, the ICC varied, respectively, from 0.89 to 0.95, 0.61 to 0.94, 0.67 to 1.00 and 0.86 to 1.00. Specifically, for questions allowing the calculation of the prevalence of self-medication and of self-administration of dietary supplements, the ICC respectively ranged from 0.87 to 1.00.

Organization of Data Collection
Before the race, and then during the period devoted to registration for the running event, two investigators proposed to female participants to answer the anonymous self-administered questionnaire. Each researcher had to count the number of refusals to participate. If female runners volunteered, the objectives of the survey were exposed orally by the investigators. The investigators drew participants’ attention to the importance of providing all the requested data accurately, reliably and completely. Investigators, previously trained, remained available to volunteers for additional information. Female volunteers then placed the completed
self-administered questionnaire in an opaque sealed urn to strictly respect the anonymity.

### Statistical Analysis

All continuous data being not normally distributed, we reported them as median and percentiles. Normality of the different data was tested using the Shapiro-Wilk test. We compared the characteristics of the individuals who took self-administered substances with those who did not by means of the Mann-Whitney test for quantitative data not normally distributed and the chi-square test for qualitative variables. A logistic regression was also performed to describe the relation between the dichotomous dependent variable (i.e., self-administration of products or not) and potential explanatory variables. We considered as potential explanatory variables those having a $p$ value lower than 0.10 in the descriptive analysis. The statistical analyses were performed using the software Statistica 10. Results were considered as statistically significant when two-tailed $p$ values were less than 0.05.

### RESULTS

A total of 136 female runners responded to the survey. The median age in our sample was 39 years [interquartile range (IQR): 27–47]. Participants’ characteristics are summarized in Table 1. Note also that 13 women refused to participate in our survey. The non-participation rate thus amounts to 8.72%.

#### Self-Administration Of Medicines

Among the 136 respondents, 47 female runners (34.6%) had taken self-medication drugs during the period immediately preceding the running (i.e., maximum last 24 h) with the aim of being physically prepared for the competition. The main reasons reported by women who indicated self-medication were: to reduce pain (14.0%), to reduce headaches (11.8%) and to improve their physical performance (6.6%) (Table 2). Non-opioid analgesics and nonsteroidal anti-inflammatory drugs were the two therapeutic agents most often cited. Moreover, 11.1% (out of the 47 women who used medicines) consumed two drugs or more. Table 3 shows that no differences were found between female runners who used self-medication drugs with those who did not regarding age, body mass index, level of education, number of health ailments and

| Variables                  | N  | %  | Median (P25–P75) |
|----------------------------|----|----|------------------|
| Age                        | 136| 39 | 39 (27–47)       |
| Body mass index            | 136| 21.8| 21.8 (19.9–23.6) |
| Level of education         |    |    |                  |
| Primary school             | 2  | 1.5|                  |
| Secondary school           | 43 | 31.6|                  |
| Post-secondary education   | 88 | 64.7|                  |
| Doctorate                  | 3  | 2.2|                  |
| Number of health ailments  | 136| 0  | 0 (0–1)          |
| Number of sports activities| 136| 1  | 1 (1–2)          |
| Number of hours of weekly  | 136| 5  | 5 (3–7)          |
| Membership in a club       |    |    |                  |
| Yes                       | 79 | 58.1|                 |
| No                        | 57 | 41.9|                 |
| Length of the race         |    |    |                  |
| 10 km                     | 97 | 71.3|                 |
| 21 km                     | 39 | 28.7|                 |
length of the race. Nonetheless, the median number of sports activities and the median time of sports practiced weekly were significantly superior in the self-medicated group ($p$ values were, respectively, 0.04 and 0.01). Female runners were also more likely to use self-medication drugs if they were a member of a sports club ($p$ value $= 0.001$).

When we inserted all variables with $p$ values less than 0.10 into a logistic regression model, we observed indeed that the probability to self-medicate was 1.66-fold (95% CI: 1.06–2.61, $p$ value $< 0.001$) increased depending on the number of sports activities, 1.13-fold (95% CI: 1.02–1.24, $p$ value $= 0.02$) increased depending on the number of hours of weekly sports activity and 2.49-fold (95% CI: 1.07–5.81, $p$ value $= 0.03$) depending on the membership in a sports club.

### Self-Administration of Dietary Supplements

Among the 136 amateur runners, 46 women (33.8%) declared having taken self-administered vitamins or minerals during the week preceding the running event. The vitamins most frequently consumed were vitamin D and vitamin C, respectively, taken by 12.5% and 5.2% of the whole study population. The main mineral consumed was magnesium (15.4%). Female runners asserted having mainly consumed these dietary supplements to prevent a potential health problem. Characteristics of women who took self-administered supplements compared to those who did not are presented in Table 4. Women who were members of a sports club were significantly more likely to consume vitamins and minerals ($p$ value $<0.001$) without medical advice. A multivariable logistic analysis confirmed that the more intense the physical activity was in terms of number of sports practiced, the higher the probability of using dietary supplements (OR 1.84, 95% CI 1.16–2.92, $p$ value $= 0.008$). It confirmed, as well, that women who were members of a sports club were more likely to use vitamin or mineral supplements (OR 4.95, 95% CI 2.02–12.11, $p$ value $<0.001$).

### Context of Self-Administration of Substances

Among the 136 female runners, 16.9% declared having taken both self-administered dietary supplements and drugs. We therefore assessed the association between the two behaviors: the self-administration of one type of substance (medicines or supplements) was positively and significantly associated with the probability to resort to self-administration of the other substance (supplements or medicines, respectively) (OR 2.75, 95% CI 1.31–5.78, $p$ value $<0.05$).

When asked on whose advice women consumed these products, most of them (43.4%) replied doing so on their own initiative. They also answered following advice of sports acquaintances (35.3%) and of family members (23.5%). Regarding where dietary supplements and medicines were obtained

| Indications          | %   | Mainly consumed substances |
|----------------------|-----|----------------------------|
| Pains                | 14.0| Ibuprofen                  |
| Headache             | 11.8| Paracetamol                |
| Improving performance| 6.6 | Vitamin D                  |
| Blocked nose         | 6.6 | Pseudoephedrine            |
| Stress               | 3.7 | Trazodone                  |
| Asthma               | 1.5 | Salbutamol                 |

Table 2 Self-reported indications for self-medication

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women mainly answered “at the pharmacy” and “from the family medicine chest” (also supplied by the formerly prescribed drugs). The acquisition of substances on the Internet and from the circle of acquaintances was also mentioned.

**Doping Potential of Consumed Products**

Among women who mentioned self-medication (34.6%), 23.4% consumed potentially doping substances, which represents 8.1% of the total sample. Two individuals (1.5%) admitted to having consumed cannabis, a formally forbidden substance, in competition. Six female runners (4.4%) disclosed having inhaled, without any professional supervision, salbutamol or formoterol, which are potentially doping substances, depending on the dose and the medical context. Pseudoephedrine, another potentially doping substance, contained in decongestant drugs, was consumed by three runners (2.2%).

**Female Runners’ Knowledge of Anti-Doping Legislation**

Among the 136 runners, 26.5% declared ignoring the existence of an official list enumerating substances considered as doping products in sports. Among the remaining 73.5% having knowledge of this list, 52.9% admitted never consulting it. Furthermore, 25.7% of the women assured knowing from which level of Table 3 Characteristics comparison between women who self-medicated and women who did not

| Variables                        | Self-medication (N = 47) |                    | No self-medication (N = 89) |                    | p value |
|----------------------------------|--------------------------|--------------------|-----------------------------|--------------------|---------|
|                                  | n  | %   | Median (P25–P75) | n  | %   | Median (P25–P75) |                       |
| Age                              | 47 | 40  | (29–51)         | 89 | 36  | (26–47)         | 0.33                   |
| Body mass index                  | 47 | 21.5| (21.1–24.3)     | 89 | 22.4| (20.4–24.2)     | 0.17                   |
| Level of education               |    |     |                 |    |     |                 | 0.74                   |
| Primary school                   | 1  | 2.1 |                 | 1  | 1.1 |                 |                       |
| Secondary school                 | 14 | 29.8|                 | 29 | 32.6|                 |                       |
| Post-secondary education         | 30 | 63.8|                 | 58 | 65.2|                 |                       |
| Doctorate                        | 2  | 4.3 |                 | 1  | 1.1 |                 |                       |
| Number of health ailments        | 47 | 0   | (0–1)           | 89 | 0   | (0–0)           | 0.51                   |
| Number of sports activities      | 47 | 2   | (1–3)           | 89 | 1   | (1–2)           | 0.04                   |
| Number of hours of weekly sports activity | 47 | 6   | (3–12)          | 89 | 4   | (3–6)           | 0.01                   |
| Membership in a club             |    |     |                 |    |     |                 | 0.001                  |
| Yes                              | 36 | 76.6|                 | 43 | 48.3|                 |                       |
| No                               | 11 | 23.4|                 | 46 | 51.7|                 |                       |
| Length of the race               |    |     |                 |    |     |                 | 0.83                   |
| 10 km                            | 33 | 70.2|                 | 64 | 71.9|                 |                       |
| 21 km                            | 14 | 29.8|                 | 25 | 28.1|                 |                       |
competition a doping test could be done, but 47.6% of them were wrong.

DISCUSSION

Prevalence of Self-Medication

Around one-third of female athletes declared using medicines or dietary supplements without medical supervision during the period immediately preceding the running event. Moreover, 16.9% used both self-administered medicines and dietary supplements, showing that female runners consuming diverse supplementations significantly tend to use medicines also, and vice versa. Other studies looking at the prevalence of self-medication in amateur athletes [12, 14] showed a slightly higher prevalence than that observed in our results (60% or more, compared to around 30% in our survey). Such discrepancies can easily be explained: these studies were only interested in self-medication as a lifelong habit. Indeed, this behavior is practiced in usual lifestyles by most individuals of the general population. In our case, we focused on self-administered drugs especially in order to be physically prepared for a specific sports event. This procedure allowed us to highlight short-term risks of this kind of behavior. Our results are more in line with a large study [13], carried out on male and female

### Table 4 Characteristics comparison between women who self-administered dietary supplements and women who did not

| Variables                          | Self-administration of dietary supplements (N = 46) | No self-administration of dietary supplements (N = 90) | p value |
|-----------------------------------|--------------------------------------------------|---------------------------------------------------|---------|
|                                   | n   | %    | Median (P25–P75) | n   | %    | Median (P25–P75) |         |
| Age                               | 46  | 42.5 | (32.0–51.0)      | 90  | 35.5 | (25.0–46.0)      | 0.07    |
| Body mass index                   | 46  | 21.3 | (19.8–23.4)      | 90  | 21.9 | (19.9–23.6)      | 0.70    |
| Level of education                |     |      |                  |     |      |                  | 0.62    |
| Primary school                    | 0   | 0.0  |                  | 2   | 2.2  |                  |         |
| Secondary school                  | 15  | 32.6 |                  | 28  | 31.1 |                  |         |
| Post-secondary education          | 29  | 63.0 |                  | 59  | 65.6 |                  |         |
| Doctorate                         | 2   | 4.4  |                  | 1   | 1.1  |                  |         |
| Number of health ailments         | 46  | 0 (0–01) |                  | 90  | 0 (0–1) |                  | 0.60    |
| Number of sports activities       | 46  | 2 (1–2) |                  | 90  | 1 (1–2) |                  | 0.005   |
| Number of hours of weekly sports activity | 46  | 6 (3–7) |                  | 90  | 4 (3–7) |                  | 0.282   |
| Membership in a club             |     |      |                  |     |      |                  | <0.001  |
| Yes                               | 38  | 82.6 |                  | 41  | 45.6 |                  |         |
| No                                | 8   | 17.4 |                  | 49  | 54.4 |                  |         |
| Length of the race                |     |      |                  |     |      |                  | 0.09    |
| 10 km                             | 37  | 80.4 |                  | 60  | 66.7 |                  |         |
| 21 km                             | 9   | 19.6 |                  | 30  | 33.3 |                  |         |
runners, which showed that up to 49% of athletes consume drugs on their own initiative just before a marathon. However, this study only focused on over-the-counter analgesic consumption.

**Context of Self-Administration of Products**

In our research, it was not surprising to detect an increase in the probability to self-administer various products with the intensification of physical activity required. Nevertheless, the fact that this probability also increases when amateur runners are members of a sports club seems more unexpected. Some studies [15–17] suggested that social environment (e.g., family members and peers) prompted subjects to consume health remedies without physician’s advice. In our study, a similar observation seemed clear: female amateur runners stated seeking advice from their family members and their sports acquaintances. Some even reported obtaining substances from their circle of acquaintances. A recent meta-analysis [18] also highlighted the importance of social influence in doping intentions.

Moreover, in accordance with other studies [19, 20], the two therapeutic agents most consumed by the female runners in our sample were non-opioid analgesics and nonsteroidal anti-inflammatory drugs (NSAIDs). However, using these pharmaceutical agents could lead to an acute risk of worsening traumatic injuries [21], and unexpected adverse effects related to these drugs may also occur (e.g., gastrointestinal, cardiovascular and renal disorders). In our study, numerous women asserted using several active substances in a combined way. The risks of drug interactions are thus multiplied and could lead to harmful consequences.

Regarding where products were obtained, the female runners frequently mentioned the family medicine chest. This probably suggests that these subjects consumed formerly prescribed drugs on their own initiative, which is an understudied practice but which requires particular attention. In addition, we noted the acquisition of substances on the Internet. The online purchase is, nonetheless, sometimes unreliable: provenance and quality of substances are not always controlled.

**Doping Potential of Products and Knowledge of the Anti-Doping Regulations**

Among female runners who consumed products without medical supervision, 23.4% have consumed potentially doping substances. Except for cannabis, which is banned in
competition, the other substances are prohibited above a predefined threshold, in and out of competition, with the exception made of a therapeutic use exemption [22]. Deplorably, it has been shown that some dietary supplements contain illegal doping substances [23, 24]. Women in our sample were likely to use dietary supplements, which they rightly supposed as legal because sold as such, but unfortunately illegally contained doping substances. This could favor a better performance and exposes athletes, potentially and unconsciously, to the risks of inadvertent doping.

Doping intentions can be highlighted within our sample. Indeed, among female runners who took self-administered products, nearly 7% clearly indicated consuming substances to improve their sports performances. This figure could be even more dramatic as we can hypothesize that some individuals declared having used a product for a therapeutic purpose when, in fact, they used it with the aim to enhance their physical performance. This is particularly true for drugs known for their non-medical use (no therapeutic purpose), such as beta 2-agonists [25], consumed by some female runners in our sample.

We also noted a lack of women’s knowledge regarding world anti-doping regulations. Indeed, controls can be conducted at any levels of competition, and the anti-doping regulations also include the possibility of control outside competition [10]. More surprisingly, more than one out of four female runners ignored the existence of the World Anti-Doping Agency prohibited list, and most of those who knew it declared never consulting it. These observations are similar to those made in a previous study [26] demonstrating that, generally, athletes have limited knowledge of anti-doping regulations.

Contributions and Limitations of Our Survey

This study has some strengths. We had the opportunity to collect a limited but sufficient sample to highlight behaviors of self-administration of various products among female runners. In other published studies, researchers focused on lifestyle habits related to self-administration of products but did not objectivize this behavior during the period immediately preceding the competition. The way we proceeded, with our questionnaire involving a particularly short recall period, we obtained comprehensive data about drugs and supplements consumed without health professional advice and with the aim to be better prepared for the race. Moreover, the perspective in which we envisaged this topic allowed us to collect a wide panel of medicinal behaviors at risk for amateur athletes. We also drew up a list of substances presenting a doping power and those being able to lead to a positive result to a doping test. Our questionnaire also shows a good reliability, as indicated by the values of the ICC (i.e., 0.9 and 1.0) for the two main outcomes. This means that if the evaluation by means of our questionnaire could be performed at different times, in a similar context of testing, it would highlight the same results.

Our research also has a number of limitations that need to be considered. First of all, we opted for a convenience sampling, which does not allow us to generalize our results to the whole population of female runners. Then, even if several statically significant relations were established in our sample, it is essential to interpret these with caution by considering them in the strict frame of our survey. Furthermore, the information bias, due to self-declaration, is the main bias inherent to
our investigation. Actually, all the data were self-reported and could have been relayed, voluntarily or not, in an inaccurate or erroneous way. Moreover, the topic approached by our study is subject to social desirability bias, despite a strict guarantee of anonymity. Therefore, we can suppose that prevalence of the practices of self-administration of medicines and dietary supplements has been underestimated in our survey. This social desirability bias is also probably related to refusal to participate (non-participation rate: 8.72%) and therefore also leads to a possible underestimation of the actual prevalence of the practice.

A season bias could also influence our findings. Indeed, in the data collected in February 2015, we observed a higher consumption of decongestant drugs (some being on the World Anti-Doping Agency prohibited list) than for the rest of the collection period.

CONCLUSIONS

Our study underlined that self-administration of medicines and dietary supplements among female amateur runners seems frequently practiced and is influenced by the intensity of physical activity and peers. A promotion of a responsible use of medicines and supplements is therefore necessary to prevent drug misadventures and protect female athletes' health.

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Compliance with Ethics Guidelines. All procedures followed were in accordance with the ethical standards of the responsible committee on human experimentation (Ethics Committee of the University Teaching Hospital of Liège, Belgium) and with the Helsinki Declaration of 1964, as revised in 2013. Informed consent was obtained from all patients for being included in the study.

Data Availability. The data sets analyzed during the current study are available from the corresponding author on reasonable request.

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