

A dry extract of *Passiflora incarnata* L. (Sedanxio®) as first intention treatment of patients consulting for anxiety problems in general practice

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ABSTRACT

The objective of the present study was to evaluate the efficacy of a dry extract of *Passiflora incarnata* L. (Sedanxio®) in patients consulting for anxiety in general practice. A total of 2928 patients were included by 219 general practitioners. Patients were evaluated at baseline and 2 weeks later using the Hamilton Anxiety Scale. Results showed a very significant improvement in anxiety scores, from 25.6 (SD = 8.3) at baseline visit to 15.4 (SD = 7.7) at follow up visit (-41%) ($p < 0.0001$). The Hamilton psychic and somatic subscores improved similarly. In addition, 15.6% of the patients could be considered in remission at visit 2 (Hamilton Anxiety Scale less than 7). These results demonstrate the interest of *Passiflora incarnata* as a first line treatment of anxiety symptoms.

Introduction

In Western countries, an increasing number of patients is suffering from anxiety disorders due to hectic modern life environment, professional and/or family stress, and also ageing. Up to a certain point, these problems can be handled by the patients themselves but, if they persist or deteriorate, they require medical advice and treatment. Besides recommendations for a alleviating daily stress, for a better life style, or even for psychological support, general practitioners (GP) will prescribe medications often to answer their patient's demands and concerns (Ansseau, 2003).

During the past decades, many patients have been treated right away with benzodiazepines (BZD), drugs known to have a high efficacy but which may also entail serious side effects, interactions or contra-indications (Ansseau, 1996). In particular, they can be responsible for drowsiness, memory difficulties, paradoxical reactions with acute aggressiveness or depressive symptoms. The most serious danger with benzodiazepines however is their potential for abuse and dependence. Therefore, the tendency today is to reduce the use of BZDs. Clearly a lot of patients suffering from tension, stress, insomnia or from mild to moderate anxiety do not need BZDs as a first intention treatment of their disorders. In this context, dry extract of *Passiflora incarnata* L. (Sedanxio®), a plant-based medication, is traditionally used to treat anxiety problems of mild to moderate severity or sleep disturbances. Several studies have suggested the efficacy of *Passiflora* in anxiety disorders (Miyasaka et al., 2007). In particular, *Passiflora* showed similar efficacy as compared to oxazepam but significantly less impairment of job performances (Akhondzadeh et al., 2001). The evaluation of activity parameters of *passiflora* dry extract capsules according to a "star" model showed moderate activity on psychic anxiety, weak effect on somatic anxiety, very weak sedative/hypnotic effect, and an absence of muscle-relaxing and antiepileptic activity (Ansseau, 2004). Large scale studies are however missing in order to define more precisely the anxiolytic activity of the compound.

Therefore, the present study was designed to assess the effect of *Passiflora* (Sedanxio®) as a first intention treatment in patients consulting their GP for anxiety disorders.

Material and methods

STUDY DESIGN

This is an open, multicentre, observational and not interventional study conducted in general practice in Belgium. A representative sample of GPs from all over the country was solicited to enrol 1-20 consecutive patients attending the practice for anxiety disorders and to whom a first intention treatment of 2 times daily 2 capsules containing 200 mg of dry extract of *Passiflora incarnata* L. (hydro alcoholic extract (60% V/V) (2:1) of the aerial parts of *Passiflora incarnata* L. Passionflower) was prescribed (visit 1). Patients were then seen 2-8 weeks later (visit 2) to assess treatment outcome and continuation.

COLLECTED INFORMATION

Age (years), gender, height (cm), weight (kg), smoking (> 10 cigarettes/day), alcohol (> 4 glasses/day) and number of concomitant drugs were recorded at visit 1 (baseline). BMI (kg/m²) was computed from weight and height. At visit 2, the duration of treatment, its continuation (no/yes), and the number of concomitant drugs were noted.

Assessment of anxiety was based on the Hamilton Anxiety Rating Scale (Hamilton, 1959) (HAM-A) which was filled out by the patients at both visits. The HAM-A consists of 14 items scored on a 5-point Likert scale (0 = not present, 1 = mild, 2 = moderate, 3 = severe, 4 = very severe) with a total score range of 0 – 56. It is generally agreed that a score <17 indicates mild severity, 18-24 mild to moderate severity, 25-30 moderate to severe, > 30 severe to very severe anxiety. Confirmed anxiety is often defined as HAM-A ≥ 20. The 14 items are, respectively, anxious mood, tension, fears, insomnia, intellectual, depressed mood, somatic (muscular), somatic (sensory), cardiovascular symptoms, respiratory symptoms, gastrointestinal symptoms, genitourinary symptoms, autonomic symptoms, and behaviour at interview.

Two subscores were calculated from the HAM-A: the psychic anxiety score (HAM-AP) equal to the sum of items 1-6 and 14, and the somatic anxiety score (HAM-AS) equal to the sum of items 7-13. Both subscores range in the interval 0-28.

OUTCOME MEASURES

To assess the treatment efficacy, the primary outcome measure was defined as the proportion of patients in remission (HAM-A ≤ 7) at visit 2.

Secondary outcome measures included absolute or relative (%) change in HAM-A, HAM-AP, and HAM-AS scores between the two visits. Improvements of individual HAM-A items were also considered, improvement for a given item being defined as a visit 2 score strictly less than visit 1 score.

STUDY POPULATION

The study or intention-to-treat (ITT) population consisted of all patients enrolled by their GPs for anxiety problems and who attended both visits. A more restricted population was defined as all patients of the ITT population aged 18-75 years and with “confirmed” anxiety (HAM-A ≥ 20).

STATISTICAL METHODS

Results were expressed as mean ± standard deviation (SD) for quantitative variables and scores, while frequency tables were used for categorical findings. For skewed distributions, the median was given together with the interquartile range (IQR). Mean values were compared by the Student t-test. McNemar test of symmetry was used to compare HAM-A item scores at the two visits.

The association between remission (primary outcome measure) and covariates was assessed by logistic regression. Odds ratios (OR) with 95% confidence intervals were calculated to measure the association between outcome and individual covariates. Multiple regression analysis was applied to analyse the relationship between a quantitative variable (e.g., change in HAM-A score – secondary outcome measures) and a set of covariates. The quality of the regression was appraised by the multiple coefficient of determination (R^2).

Before any calculations, outliers were detected and discarded from the analysis. A result was considered as an outlier if outside the interval $Q1 - 1.5 H$ and $Q3 + 1.5 H$, where $Q1$ and $Q3$ are respectively the 25th and 75th percentiles (quartiles) of the sample distribution and $H = Q3 - Q1$, the H-spread.

Results were considered significant at the 5% critical level ($p < 0.05$). Calculations were performed with the SAS (version 9.2 for Windows) and S-PLUS (version 7.1) statistical packages.

Results

A total of 219 GPs participated in the study. They enrolled 2,928 patients consulting for anxiety problems and seen at both visits (recruitment rate: 13.4 ± 6.9 patients/GP).

DEMOGRAPHIC CHARACTERISTICS

The 2928 patients constituted the study population. Their characteristics are described in Table 1.

Table 1. Characteristics of the 2928 patients of the ITT population

| Variable | Category | Mean \pm SD or No. (%) |
|--------------------------|-----------------|--------------------------|
| Age (years) | | 43.8 \pm 17.2 |
| Gender | Men | 959 (33.2) |
| | Women | 1933 (66.8) |
| Height (cm) | | 168.9 \pm 8.51 |
| Weight (kg) | | 70.0 \pm 13.3 |
| BMI (kg/m ²) | | 24.5 \pm 4.22 |
| Smoking | > 10 cig/day | 860 (31.6) |
| Alcohol | > 4 glasses/day | 416 (15.5) |
| Concomitant drugs* | Number | 2.1 \pm 1.3 |
| | 0 | 91 (7.0) |
| | 1 | 536 (41.3) |
| | 2 | 335 (25.8) |
| | 3 | 188 (14.5) |
| | ≥ 4 | 148 (11.4) |

* Only available for 1298 patients

Patients were on average 43.8 ± 17.2 years old (range: 11 – 96) and there was a clear majority of women (66.8%). The mean BMI was 24.5 ± 4.22 kg/m² (range: 10.5 – 66.4 kg/m²). The proportion of smokers and drinkers were 31.6% and 15.5%, respectively. The number of concomitant drugs was only known for 1298 (44.3%). Almost all patients (93 %) took another medication and had on average 2.1 ± 1.3 concomitant drugs.

BASELINE ANXIETY STATUS

The distributions of the 14 items of the HAM-A scale and of the total score and subscores at baseline are summarized in Table 2. It is seen that the most affected items (i.e., proportion of subjects with a score ≥ 2) were insomnia (87.5%), anxious mood (84.7%) and tension (82.8%). The least affected items were autonomic symptoms (53.3%), somatic sensory (51.6%) and genitourinary symptoms (31.0%). The distribution of the total HAM-A score depicted in Figure 1 appears to be fairly Gaussian with a mean value of 25.7 and a SD of 8.3, the median being 26.0. The proportion of patients with “confirmed” anxiety (HAM-A ≥ 20) was equal to 78.5%.

Table 2. Distribution of the 14 items of the HAM-A at baseline ($n = 2928$ patients)

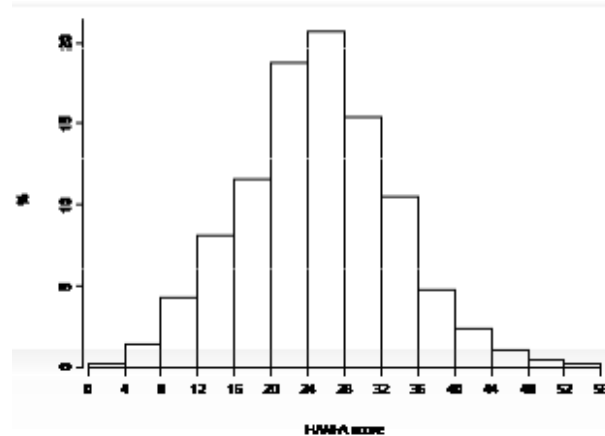
| Item | Mean \pm SD | Proportion |
|-------------------------------|----------------|--------------------|
| 1. Anxious mood | 2.4 ± 0.90 | 84.7 |
| 2. Tension | 2.3 ± 0.90 | 82.8 |
| 3. Fears | 1.7 ± 1.1 | 58.1 |
| 4. Insomnia | 2.5 ± 0.94 | 87.5 |
| 5. Intellectual | 1.9 ± 0.96 | 67.8 |
| 6. Depressed mood | 1.9 ± 1.0 | 64.9 |
| 7. Somatic (muscular) | 1.9 ± 1.0 | 65.4 |
| 8. Somatic (sensory) | 1.5 ± 1.0 | 51.6 |
| 9. Cardiovascular symptoms | 1.8 ± 0.98 | 63.9 |
| 10. Respiratory symptoms | 1.6 ± 1.0 | 55.2 |
| 11. Gastrointestinal symptoms | 1.8 ± 1.1 | 60.9 |
| 12. Genitourinary symptoms | 1.0 ± 1.0 | 31.0 |
| 13. Autonomic symptoms | 1.6 ± 1.0 | 53.3 |
| 14. Behaviour at interview | 1.9 ± 0.92 | 69.4 |
| HAM-A total score | 25.7 ± 8.3 | (range: 4 – 56) |
| HAM-AP score | 14.6 ± 4.4 | (range: 0 – 28) |
| HAM-AS score | 11.1 ± 4.9 | (range: 0 – 28) |

Finally, it is worth mentioning that the HAM-A psychic score was on average about 3.1 points higher than the corresponding somatic score (14.6 ± 4.4 for HAM-AP vs. 11.1 ± 4.9 for HAM-AS), confirming the results of the items in Table 2.

TREATMENT CHARACTERISTICS

The median time interval between the two patient visits was 22 days (IQR: 15 – 30 days) and the median treatment duration with Sedanxio® was 4 weeks (IQR: 2 – 4 weeks). The mean number of tablets taken per day was 3.4 ± 1.1 (range: 1 – 9), corresponding to a mean total dose of dry extract of *Passiflora incarnata L.* of $17,617 \pm 11,494$ mg (Median 16,800 mg; IQR 11,200 – 22,400 mg). At visit 2, the treatment was pursued in 80.2% of the patients.

Figure 1. Distribution of the HAM-A score at baseline in 2928 patients



TREATMENT EFFICACY: PRIMARY OUTCOME MEASURE

The proportion of patients in remission (HAM-A \leq 7) at visit 2 was equal to 15.6% (95% CI: 14.2 – 17.1%).

By logistic regression, it was found that remission was not affected by gender ($p=0.38$), smoking ($p=0.79$) and treatment duration ($p=0.47$). By contrast, remitters were significantly younger than non-remitters (37.6 ± 16.4 vs. 44.9 ± 17.0 years, $p<0.0001$), their BMI was slightly lower (23.8 ± 4.0 vs. 24.5 ± 4.2 kg/m², $p=0.0029$), they were less often drinkers (9.0 vs. 16.4%, $p=0.0006$), they had less often concomitant drugs (82.7 vs. 94.2%, $p<0.0001$), their HAM-A score at baseline was lower (16.7 ± 6.8 vs. 27.3 ± 7.4 , $p<0.0001$), and they took less Sedanxio® tablets per day (3.2 ± 1.2 vs. 3.4 ± 1.1 , $p<0.0001$).

When combining these factors into a multivariate logistic regression analysis, it turned out that only a low HAM-A score at baseline (OR = 1.26, 95% CI: 1.23 – 1.30) and a younger age (OR = 1.02, 95% CI: 1.01 – 1.03) were positively associated with remission.

TREATMENT EFFICACY: SECONDARY OUTCOME MEASURES

The total HAM-A score at visit 2 was 15.4 ± 7.7 (see Figure 2), thus yielding a highly significant ($p<0.0001$) decrease of 10.2 ± 6.12 points from baseline. In terms of relative drop, the corresponding HAM-A change averaged $41 \pm 22\%$ (see Table 3). Multiple regression analysis showed that the HAM-A decrease was significantly higher for elevated HAM-A baseline score ($p<0.0001$) and when treatment duration was longer ($p=0.030$). By contrast, it was

significantly lower for older patients ($p=0.0010$) and higher treatment doses ($p=0.021$). The quality of the regression however was low ($R^2=0.19$).

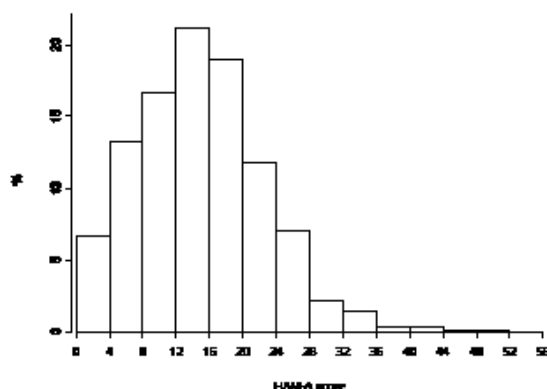
As seen in Table 3, the Hamilton psychic (HAM-AP) and somatic (HAM-AS) subscores also improved significantly from baseline after treatment. The HAM-AP score dropped by 5.7 ± 3.4 points or by $40 \pm 22\%$ ($p<0.0001$), and the HAM-AS score decreased by 4.6 ± 3.5 points or $42 \pm 30\%$ ($p<0.0001$).

Table 3. Change in HAM-A score after treatment ($n = 2928$ patients)

| Variable | N | Visit 1 | Visit 2 | Change | p-value |
|----------|------|----------------|----------------|----------------|-----------|
| HAM-A | 2344 | 25.6 ± 8.3 | 15.4 ± 7.7 | 10.2 ± 6.1 | <0.0001 |
| HAM-AP | 2373 | 14.5 ± 4.3 | 8.9 ± 4.3 | 5.7 ± 3.4 | <0.0001 |
| HAM-AS | 2359 | 11.1 ± 4.9 | 6.5 ± 4.0 | 4.6 ± 3.5 | <0.0001 |

At visit 2, all individual items scores of the HAM-A dropped significantly from baseline ($p<0.0001$). Table 4 displays for each item the mean \pm SD values at visit 2, the proportion of subjects who dropped by at least one point of the item scale, as well as the proportion of patients with an item score ≥ 2 . It is seen that for almost all items (except genitourinary symptoms), a majority of patients had at least a 1-point decrease when compared to baseline. McNemar test confirmed that there was a highly significant downward shift for all items ($p<0.0001$).

Figure 2. Distribution of the HAM-A total score at visit 2 in 2928 patients



When comparing the proportions of patients with an item score ≥ 2 at visit 2 with those at baseline (see Table 2), there was again a clear improvement in the percentages. For example, insomnia which affected 87.5% of the patients at baseline did affect only 46.6% of the patients at visit 2. Overall, this item was also the most markedly improved (74.6% with at least 1-point change), followed by anxious mood (72.3%) and tension (69.1%).

RESTRICTED POPULATION

When restricting the ITT population to patients aged 18 – 75 years with a baseline HAM-A score ≥ 20 (confirmed anxiety), a subsample of 1745 (59.6%) subjects was obtained. The demographic characteristics of these subjects were very similar to those of the general population: age (43.4 ± 14.9 years), gender (66.9% female), BMI (24.5 ± 4.3 kg/m²), smoking (33%),

alcohol (17.2%), and no. of concomitant drugs (1.9 ± 1.2). The total HAM-A score averaged 28.7 ± 6.4 , obviously slightly higher, and so were the HAM-AP and HAM-AS subscores, respectively, 15.9 ± 3.5 and 12.7 ± 4.0 . The median time interval between the two visits was 22 days (IQR: 15 - 29 days) and the median treatment duration was 4 weeks (IQR: 2 - 4 weeks). The mean number of medication tablets was 3.5 ± 1.1 (range: 1 - 9) corresponding to a total mean dose of $17,976 \pm 11,560$ mg (median 16,8 mg; IQR 11,200 - 22,400 mg) as in the total study population. At visit 2, the treatment was continued in 82.6% of the patients.

Table 4. Characteristics of HAM-A individual items at visit 2

| Item | Score at visit 2 | Proportion (%) with | Proportion (%) |
|---|------------------|---------------------|----------------|
| 1. Anxious mood | 1.5 ± 0.79 | 72.3 | 45.8 |
| 2. Tension | 1.4 ± 0.80 | 69.1 | 43.6 |
| 3. Fears | 1.1 ± 0.86 | 51.8 | 29.3 |
| 4. Insomnia | 1.5 ± 0.88 | 74.6 | 46.6 |
| 5. Intellectual | 1.1 ± 0.84 | 59.6 | 30.5 |
| 6. Depressed mood | 1.2 ± 0.85 | 56.9 | 31.7 |
| 7. Somatic (muscular) | 1.1 ± 0.85 | 61.0 | 29.2 |
| 8. Somatic (sensory) | 0.9 ± 0.80 | 50.9 | 21.4 |
| 9. Cardiovascular symptoms | 1.0 ± 0.80 | 61.5 | 25.2 |
| 10. Respiratory symptoms | 0.9 ± 0.80 | 56.3 | 19.9 |
| 11. Gastrointestinal symptoms | 1.0 ± 0.85 | 58.9 | 26.1 |
| 12. Genitourinary symptoms | 0.6 ± 0.81 | 34.9 | 13.4 |
| 13. Autonomic symptoms | 0.9 ± 0.79 | 54.8 | 21.1 |
| 14. Behaviour at interview | 1.1 ± 0.79 | 66.4 | 27.3 |
| . Significant drop from baseline for all items ($p < 0.0001$) | | | |

As far as the primary outcome measure was concerned, a total of 7.1% patients were found to be in remission ($\text{HAM-A} \leq 7$). This is less than half of the proportion (15.6%) found in the general population, indicating that the treatment efficacy was lower when considering patients with moderate to severe or very severe anxiety ($\text{HAM-A} \geq 20$).

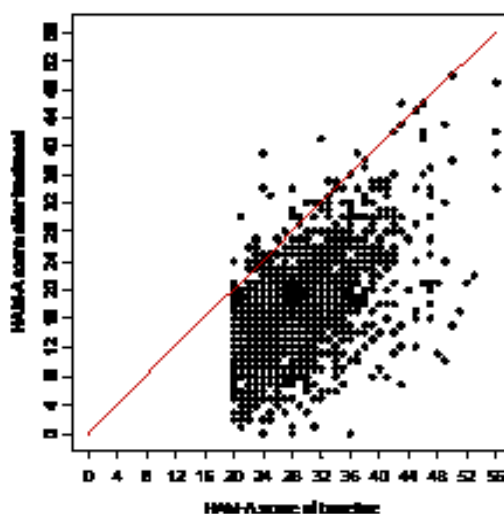
For secondary outcome measures, as seen in Figure 3, a significant decrease was found between the two visits for the total HAM-A score ($40 \pm 20\%$; $p < 0.0001$). An improvement also occurred for the psychic HAM-AP subscore ($38 \pm 20\%$; $p < 0.0001$) and the somatic HAM-AS subscore ($41 \pm 26\%$; $p < 0.0001$). These findings were quite comparable to those obtained for the total population (see Table 3). Likewise, all 14 items of the HAM-A scale improved significantly after treatment ($p < 0.0001$), with special mention for insomnia, anxious mood, tension and behaviour at interview.

Discussion

The present study was designed to assess the efficacy of a first intention treatment with a dry extract of *Passiflora incarnata* L. (Sedaxio® capsules) in patients consulting their general practitioners for anxiety disorders. The observational, non-interventional nature of the study

necessarily induced a number of biases and limitations (e.g., no control group, lenient inclusion and exclusion criteria, lack of control on some managerial and clinical factors, absence of randomization, presence of spurious results), which were partly tempered by the large size of the population of patients enrolled and the use of robust statistical techniques to avoid outlying and highly influential observations. It has been evidenced that conclusions drawn from the entire patient population were very similar to those obtained from the restricted subgroup of 18 – 75 years old patients with confirmed anxiety (HAM-A \geq 20).

Figure 3. Improvement of the HAM-A total score from baseline after Sedaxio® treatment (n=1745 patients) with confirmed anxiety



The present study showed that two thirds of the patients consulting for anxiety disorders in general practice were women. Fifty percents of the patients were in the age range 30 – 56 years and with moderate to severe overweight (BMI \geq 23.9 kg/m²). About one third was smokers and 15% were alcohol drinkers. Data about concomitant drugs were captured for less than half of the patients but revealed that 93% of them did take other medications. The demographic characteristics of the study patients seem to correspond pretty well with those of the population attending a GP visit for depressive and/or anxious symptoms. The anxiety profile of the patients as assessed by the HAM-A scale varied widely from mild to very severe cases. We found that a substantial proportion of the subjects enrolled (approximately 60%) had “confirmed” anxiety (HAM-A \geq 20).

Despite the potential limitations of the study design, first intention treatment with a dry extract of *Passiflora incarnata L.* (capsules) demonstrated an overall remission rate of 15.6% for the general study population and of 7.1% for the subgroup of moderate to very severe anxiety patients. Likewise, total HAM-A score, HAM-AP and HAM-AS subscores, as well as all 14 individual items of the HAM-A significantly improved at visit 2 (treatment outcome) as compared to baseline. Insomnia, anxious mood and tension items were particularly reduced by the treatment.

The beneficial efficacy of Sedanxio® treatment of anxiety evidenced in this study has to be interpreted with caution since no control was made of other anxiolytics and antidepressant drugs taken by the patient (such as BZDs). Moreover, although the selection of patients was such that Sedanxio® was prescribed as first intention treatment, there is no guarantee that patients previously or currently treated with other drugs were not massively included in the study.

When analysing factors likely to affect the remission rate, it was found that patients with elevated HAM-A score at initiation of the treatment (baseline), i.e., highly anxious subjects, were less likely to remit than the others. This finding seems logical as it is not really expected that Sedanxio® treatment, even during a prolonged period of time, will cure patients with a long history and/or severity of anxiety. However, it was also observed that older patients did perform worse than younger ones in terms of remission. This observation deserves some attention since not all elderly patients exhibit a long history of anxiety disease.

Assessment of anxiety in older patients with the HAM-A scale may not be appropriate or sufficiently refined to assess severity.

When considering covariates potentially influencing the drop in HAM-A score and subscores after Sedanxio® treatment, it was found that the higher the HAM-A score at baseline, the more important the drop after treatment. The latter however was often not sufficient to reach remission. This observation is made in many studies on anxiety and depression. For patients with high baseline scores, the range of the potential decrease is wider than for patients with low baseline scores, because of the numerical score of the scale itself. Finally, age was confirmed to be negatively correlated with improvement of anxiety scores. Indeed, older subjects had more difficulties to bring their anxiety severity level down than younger patients.

In the present study, compliance to the treatment was not recorded. It is therefore difficult to assess its impact on the study results. Due to the large number of patients enrolled, the assumption can be made that a majority of them took the capsules regularly and respected the prescribed doses. Although dose related information was also subject to caution, no significant relationship was evidenced between dose prescribed and treatment effect on anxiety remission and severity. This may support the assumption that GPs administered the appropriate dose regimen to the patient's individual anxiety status.

The results of the present study support anxiolytic activity of Sedanxio®. They confirm several reports. In particular, a placebo-controlled study showed that in outpatient surgery, the administration of Sedanxio® as a premedication reduces anxiety without inducing sedation (Movafegh et al., 2008). Similarly, oral preoperative intake of Sedanxio® suppresses the increase in anxiety before spinal anaesthesia without changing psychomotor function test results, sedation level, or hemodynamics (Aslanargun et al., 2011). A recent systematic review of nutritional and herbal supplements for anxiety and anxiety-related disorders showed improvement in symptomatology without the risk of serious site-effects (Lakhan & Vieira, 2010).

Sedanxio® could represent an interesting alternative for benzodiazepines. Indeed, Sedanxio® appears devoid of site-effects typical of benzodiazepines, in particular, sedation and memory disturbances (Ansseau and Sabbe, 2003).

In addition, the major limitation of benzodiazepines comes from their potential for abuse and dependence. In particular, they can be responsible for a withdrawal syndrome which can be of high severity with panic attacks, seizures, confusion, hyperesthesia. Sedanxio® appears devoid of such abuse and/or dependence potential.

In conclusion, the present Belgian open, observational, non-interventional study on patients consulting for anxiety problems in general practice has demonstrated a remission rate (HAM-A ≤ 7) of 7 - 15% and a highly significant reduction in HAM-A scores and subscores, as well as in individual item scores, after 2 - 4 weeks of first intention treatment with a dry extract of *Passiflora incarnata L.* (capsules). The total HAM-A score decreased by 41 % between the two visits. The most markedly items improved were insomnia followed by anxious mood and tension. At visit 2, the treatment was continued in 80.6% of the patients.

Despite the limitations of observational studies, the salient findings of this study add therapeutic evidence on the beneficial effects of Sedanxio® in the care management of anxiety in general practice.

Résumé

L'objectif de cette étude était d'évaluer l'efficacité d'un extrait sec de *Passiflora incarnata L.* (Sedanxio®) chez des patients consultant leur médecin traitant pour de l'anxiété. Un total de 2928 patients ont été recrutés par 219 médecins généralistes. Les patients étaient évalués au début du traitement et 2 semaines plus tard avec l'échelle d'anxiété de Hamilton. Les résultats mettent en évidence une amélioration très significative dans les scores d'anxiété, de 25.6 (SD = 8.3) à la visite 1 à 15.4 (SD = 7.7) à la visite 2 (-41%) ($p < 0.0001$). Les sous-scores d'anxiété psychique et somatique de l'échelle de Hamilton se sont également améliorés. De plus, 15.6 % des patients pouvaient être considérés comme en rémission à la visite 2 (Echelle d'anxiété de Hamilton inférieure à 7). Ces résultats démontrent l'intérêt de la passiflore comme traitement de première ligne des symptômes anxieux.

Samenvatting

Het doel van deze studie bestond erin om de werkzaamheid van een droog extract van *Passiflora incarnata L.* (Sedanxio®) te evalueren bij patiënten die een huisarts consulteren voor angst. In totaal werden 2928 patiënten gerekruteerd door 219 huisartsen. De patiënten werden in het begin van de behandeling en twee weken later geëvalueerd met de Hamilton angst schaal. De resultaten tonen een zeer significante verbetering van de angst score, van 25.6 (SD=8.3) bij het eerste bezoek naar 15.4 (SD= 7.7) bij het tweede bezoek (-41%) ($p < 0.0001$). Zowel de score van de psychische angst als deze van de somatische angst zijn verbeterd. Daarenboven zijn al 15.6 % van de patiënten in remissie bij het tweede bezoek (Hamilton angstscore onder de 7). Deze resultaten tonen het belang van passiflora in de eerste lijnsbehandeling van de angst symptomen.

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