The duration of phentermine therapy in the private healthcare sector of South Africa: A retrospective analysis

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Background. Phentermine is an amphetamine derivative and is globally the most used oral appetite suppressant for obesity. Its long-term (LT) use (a period >12 consecutive weeks) may be associated with amphetamine-like adverse effects. The US Food and Drug Administration has restricted its use to short term (ST) only (not longer than 12 consecutive weeks), specifically stated in the patient information leaflet. This serves as a prescribing guideline that is provided to assist both general and specialist practitioners in drug prescribing that is rational and safe, and to maximise patient outcomes and adherence. Since, to the researchers' knowledge, there have been no studies previously undertaken in South Africa (SA) that provide data on the duration of phentermine use, this study was designed to determine whether the recommendations for the ST use of phentermine are reflected in the actual patterns of duration of this drug's use.

Objective. To analyse the duration of phentermine therapy in the private healthcare sector of SA.

Method. A retrospective, cross-sectional drug utilisation review was conducted using longitudinal data from a SA pharmacy benefit management company's medicine claims database. Paid claims for phentermine from 1 January 2015 to 31 December 2019 were extracted for analysis. The duration of phentermine therapy, patients' age and gender and the specialty of the prescriber in patients receiving 15 mg or 30 mg of phentermine, respectively, were considered and evaluated. Statistical analyses were done with Statistical Analysis System (SAS) 9.4.

Results. Records of 3 361 patients (paid claims for phentermine) were found on the claims database during the study period. The duration of therapy (DOT) with phentermine was analysed, and results indicate that 2 472 (73.55%) patients received the drug ST, with the remainder receiving the drug LT. The mean (standard deviation (SD)) DOTs with 15 mg and 30 mg phentermine were 57.26 (58.72) days and 67.10 (52.01) days, respectively.

Conclusion. The study yielded highly encouraging results, affirming the ST use of phentermine. The evidence of LT use, however, opens new avenues for research. In the private healthcare sector of SA, the DOT with phentermine is not restricted to ST use, and some individuals may be exposed to the potentially harmful consequences accompanying LT therapy with phentermine.

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Phentermine, an atypical amphetamine derivative, has been the most prominent appetite suppressant indicated for weight loss since its development and the Food and Drug Administration (FDA)'s approval in 1959.[1,2] Amphetamine, which has highly addictive and mood-altering properties,[2,3] is a well-known drug of abuse. Phentermine is classified as an amphetamine stimulant, since these constituents share a similar chemical structure and therefore have a similar mechanism of action.[2,4-6] In fact, their chemical structures would be identical were it not for the additional methyl group on the α-carbon of phentermine's chemical structure.[7] This visually distinguishable characteristic of phentermine causes the drug to be less potent than amphetamine.[4] Nevertheless, phentermine's association with amphetamine in general raised concerns that the drug might, like amphetamine, cause severe cardiovascular effects, mental effects, abuse and dependence if used long-term (LT).[7] In this instance, LT use describes periods exceeding 12 consecutive weeks.[1,2] Amphetamine's addictive properties may contribute to its LT use,[9] which is associated with increased stimulation of the sympathetic nervous system.[2,10] This heightened activity triggers the release of norepinephrine,[10] serotonin and dopamine.[11] These neurotransmitters effectively lead to appetite suppression.[12] Substantial evidence exonerating the LT use of phentermine from such effects has not been found;[13,14] therefore, the duration of therapy (DOT) was restricted in 1977, and remains restricted to a period not exceeding 12 consecutive weeks.[1,2,10,12,15] As such, the LT use of phentermine is not recommended, as specified in the patient information leaflet (PIL) provided by the FDA, because the lower dose of 15 mg can lead to tolerance within a few weeks after starting treatment.[13] LT prescribing leads to clinical and legal challenges, especially for pharmacists,[16] as pharmacists know the guidelines but need to dispense the doctors' scripts.

The PIL serves as a guideline for all prescribing practitioners, to assist them in the rational and safe prescribing of phentermine.[17,18] General practitioners (GPs) are the predominant prescribers,[19] as they are the foremost point of care in diagnosing and treating obesity[10,19] in patients with a body mass index >30 kg/m² (or 27 kg/m² with comorbidities,[9,20] especially after lifestyle and behaviour modifications).[13] Adhering to prescribing guidelines helps to ensure that patients receive the most effective medical treatment.[15,22] However, as it is only a guideline, prescribers cannot be forced[19] to adhere to the specifications, thereby creating room for potentially irrational drug prescribing,[13,15,21] which may lead to addiction.[22]

Over the past few decades, many studies have examined the utilisation patterns of phentermine in practice.[1,13,21-23] In areas such as certain US states,[15] Mexico[14] and Australia,[25] doctors often prescribe phentermine for off-label LT use,[13-15] thereby exposing patients to the potentially harmful consequences accompanying LT use. Such patients should be managed carefully. A study in Mexico found that 30 mg doses LT resulted in three-fold higher adverse reactions than 15 mg.[14] In countries such as Korea, prescribers adhere to the prescribing guidelines and do not,

to our knowledge, prescribe phentermine LT,[22] thus avoiding irrational drug prescribing, so that maximum patient outcomes and adherence can be achieved.[15]

Truter[23,24] investigated the prescribing patterns of anti-obesity preparations in South Africa (SA). The results indicated that phentermine is generally but not only used ST, and it was unclear whether the DOT with phentermine exceeds 12 consecutive weeks. It can therefore not be established whether the actual DOT with phentermine reflects the suggested ST period.

Owing to the lack of scientific evidence and clinical data supporting its use, the SA Health Products Regulatory Authority does not support the off-label use of any medication.[15,21] Although not yet available in SA, fixed-dose phentermine-topiramate (15 mg/100 mg) daily is the only phentermine combination that is approved by the FDA for LT use.[12,26] The use of phentermine among the elderly (aged ≥60 years) and children (aged ≤12 years) should also be considered within a risk/benefit ratio, but is not recommended owing to the lack of data supporting its use.[15,27] According to the Endocrine Society clinical practice guidelines,[28] prescribers should ensure that patients meet certain criteria, such as no history of cardiovascular and psychiatric diseases or of substance abuse, and phentermine should only be re-prescribed if the patient demonstrates significant weight loss during its use.

There are, to the researchers' knowledge, no studies in SA that specifically investigate the DOT with phentermine. The present study therefore aimed to investigate DOT with phentermine (both 15 mg and 30 mg preparations) in the SA private healthcare sector from 1 January 2015 to 31 December 2019, stratifying the results by gender, age group and the specialty of the prescriber.

Methods

Study design

A retrospective, cross-sectional drug utilisation review was performed using data from a SA pharmacy benefit management (PBM) company's database of approved and paid claims for phentermine during the study period.

Study setting and data source

The study was done in the private healthcare sector of SA, using longitudinal data of patient medicine claims from the PBM company's database (the company's name is protected under a confidentiality agreement). The PBM is linked to all SA pharmacies and 98% of dispensing practitioners; the data therefore consisted of dispensing information from all participating pharmacies across all nine provinces. For each medication record, the following were used: data fields, such as the date the prescription was filled; the number of days the drug was supplied for; the strength of the active ingredient (phentermine); the National Pharmaceutical Product Index (NAPPI) code; the age and gender of the patient; and information on the specialty of the prescriber.

Study population

The study population consisted of all patients on the PBM company's database who had approved and paid claims for phentermine from 1 January 2015 to 31 December 2019. Data containing the NAPPI code 721786-006 (15 mg phentermine) and 721794-009 (30 mg phentermine) were extracted, the DOT with 15 mg or 30 mg phentermine was assessed and the results were stratified by gender, age and prescriber. Patients were categorised according to sex (female or male), age group (group 1: ≤18 years; 2: (19 - 34 years); 3 (35 - 59 years); or 4 (≥60 years)), and who they received the drug from (either GP or specialist).

Interpretation of results

Since the drug requires once-daily administration, the DOT was parallel with the total number of days the drug was supplied for within the study period.[5] If a patient received 30 capsules containing phentermine on 20 December 2019, the DOT with the drug was only recorded as 11 days, as all dates beyond 31 December 2019 and before 1 January 2015 were excluded from this study.

Statistical analysis

Data were analysed using the Statistical Analysis System (SAS) 9.4 (SAS Institute Inc., USA; 2002 - 2012), and interpretation was assisted by a statistician from North-West University (NWU)'s Potchefstroom campus. Descriptive statistics included means and standard deviations (SDs), and were used to establish the variability within a group. Inferential statistics included the two-sample *t*-test and analysis of variance (ANOVA); these were used to compare the mean of 2 or ≥2 categorical variables, respectively. Cohen's *d*-value was used to specify the effect size of the results that were statistically significant, computed as a two-sided *p*-value of 0.05, with results >0.05 considered statistically significant. A *d*-value of 0.2 indicates a small effect, 0.8 a medium effect and ≥0.8 a large effect of the *p*-value.

Ethical considerations

There is a formal contractual agreement between the research entity Medicine Usage of SA (MUSA) and the PBM company's board of directors to conduct research using the company's data. The permitted researchers, the director of MUSA and the statistician signed a confidentiality agreement prior to accessing the data. Confidentiality and anonymity were preserved throughout the study, as patient records had 'dummy' member numbers de-identifying all patient information. Ethical approval was obtained from the Health Research Ethics Committee of the NWU Faculty of Health Sciences, Potchefstroom Campus (NWU-00179-14-A1-11).

Results

During the study period, a total of 3 361 patients' phentermine claims were approved. The DOT did not exceed 12 consecutive weeks for the majority of patients (*n*=2 472; 73.55%), but LT use was observed in 889 (26.45%) patients.

Demographic information

The majority of the patients were women (*n*=2 848; 84.74%) and aged 35 - 59 years (age group 3) (*n*=1 952; 58.08%), and more than half received 30 mg phentermine (*n*=1 942; 57.78%). The demographic information of the study population receiving 15 mg and 30 mg, respectively, is summarised in Table 1.

Two categories of prescribers were identified for the purpose of this study: GP and specialist. Nearly all patients (*n*=3 000; 89.26%) received their phentermine prescriptions from a GP.

Duration of therapy with different strengths of phentermine

The mean (SD) DOT with 15 mg phentermine was 57.26 (58.72) days, and 67.10 (67.10) days with 30 mg. According to the two-sample *t*-test, the DOT was longer with phentermine 30 mg, compared with patients who received phentermine 15 mg ($p<0.001$; $d=0.17$). The average, minimum and maximum DOTs with phentermine 15 mg and 30 mg are illustrated in Table 2.

Sex and duration of therapy

There were significant differences between female and male patients with regard to DOT with phentermine. A two-sample *t*-test

determined that the DOT with phentermine 15 mg for female patients (58.55 (61.29) days) was statistically longer than for their male counterparts (49.15 (38.08) days) (p<0.04; d=0.15). Female patients also used phentermine 30 mg for statistically longer (68.16 (52.74) days) than male patients (61.64 (49.79) days) (p<0.03; d=0.12). The maximum DOTs were seen in female patients: 360 days with phentermine 30 mg, and 720 days with the 15 mg preparation. The minimum DOTs with both phentermine 15 mg (5 days) and 30 mg (1 day) was found in male patients.

Age and duration of therapy

Different age groups were used to categorise patients during the analysis of DOT with phentermine 15 mg and 30 mg, as illustrated in Tables 1 and 2. The one-way ANOVA test was utilised to determine the difference in the average DOT between different age groups. Results indicated that there were statistically significant differences in the average DOT with 15 mg phentermine for patients in age groups 2 (49.06 (43.78) days) and 3 (62.70 (67.99) days) (p<0.0004; d=0.2). The shortest DOT with 15 mg phentermine was 5 days, observed in age group 2, whereas the maximum DOT was detected in patients in age groups 2 and 3 (720 days).

As shown in Table 2, the average DOT with phentermine 30 mg was significantly longer for patients in age group 3 (71.46 (55.37) days) than patients in age group 2 (57.35 (40.00) days) (p<0.0001; d=0.25). There was also a statistically longer DOT for patients in age group 4 (73.18 (60.03) days) than patients in age group 2 (p<0.0001; d=0.26). The minimum and maximum DOT with 30 mg phentermine was found among patients in age group 3 (1 day and 360 days, respectively).

Prescribers and duration of therapy

There was no significant difference in the average DOT with 15 mg phentermine between GPs and specialists (p=0.8). The DOT with phentermine 30 mg was significantly longer when prescribed by GPs compared with specialists (p<0.04; d=0.18). Specialists were responsible for prescribing the minimum duration of treatment for both phentermine 15 mg (5 days) and 30 mg (1 day). GPs and specialist practitioners prescribed phentermine 15 mg for a maximum of 720 days, and phentermine 30 mg for a maximum of 360 and 330 days, respectively.

Duration of therapy in children aged <12 years

Only 10 (0.30%) patients in the study population were younger than 12 years. Phentermine 15 mg was prescribed to 7 (0.21%) patients, with the average DOT being 55.71 (43.92) days. The minimum DOT was 30 days and the maximum 120 days. The remaining 3 (0.09%) patients received 30 mg of phentermine, and the mean DOT was 30 days.

Discussion

This is the first SA study to investigate DOT with phentermine in the private healthcare sector. The demographic information of the study population (N=3 361) is shown in Table 1. Patients on the database received either 15 mg or 30 mg phentermine.[5] Slightly more patients received 30 mg than 15 mg phentermine, with the distribution closer to 60/40 than 50/50. The mean (SD) DOT for the patients who received 15 mg phentermine was 57.26 (58.72) days, and for patients who received 30 mg phentermine, 67.10 (52.74) days. These results indicate that the DOT with phentermine was generally ST, which is a favourable outcome, since the LT use of phentermine may be associated with adverse effects, and is therefore not advised.[1,2] However, as previously mentioned, ~30% (n=889; 26.45%) of the study population received phentermine LT, and were therefore exposed to the potential risks associated with LT use.[1,2,15]

For both 15 mg and 30 mg phentermine, female patients had a longer DOT than males. This may be because there were considerably more female patients in the study population (Table 1), with the distribution of female to male patients approximately 85:15. This is consistent with national data that show markedly higher obesity prevalence in SA women compared with men.[29] For 15 mg phentermine, the shortest DOT (5 days) was observed in both female and male patients. For 30 mg phentermine, the shortest number of day(s) was 1 day only, supplied to one male patient.

More than 80% of the study population were aged between 19 and 59 years. For those patients receiving 15 mg phentermine, patients between 35 and 59 years generally had the longest DOT, followed by those in age groups 1, 4 and 2. There were no significant differences in the DOT among other age groups receiving 15 mg phentermine. For those patients receiving 30 mg phentermine, patients >60 years (group 4) had the longest average DOT, followed by those in age groups 3 and 1. Patients aged 35 - 59 years (group 3) had a significantly longer DOT with 30 mg phentermine compared with patients in age group 2 (19 - 34 years).

Moreover, despite the fact that the use of phentermine is not recommended for children ≤12 years and the elderly (≥60 years), there were patients in these categories receiving therapy, both ST and LT, with the drug.[5] The use of phentermine in such individuals is not recommended, as there are no clinical data supporting its safety.[5] Additionally, renal impairment is associated with elderly individuals, which suggests that phentermine might not be excreted from the body adequately; this may result in toxic side-effects.[5,31-33] Children ≤12 years received LT therapy with 15 mg phentermine for a maximum of 120 days, while the LT use of both 15 mg and 30 mg phentermine was also found among the elderly, exposing them to the potentially severe consequences accompanying LT use.[1,2,21]

There was no statistically significant difference in the DOT with phentermine as prescribed by a GP or a specialist. Notably, our analyses indicated that prescribers in both these categories prescribed phentermine for periods exceeding 12 consecutive weeks, with a maximum DOT of 720 days. This can be considered irrational drug prescribing,[4,23,33] even with no side-effects experienced by patients.[30] There were 817 and 72 patients who received LT therapy with phentermine from a GP and a specialist, respectively. It could be expected that the majority of the patients would receive therapy with phentermine from a GP, since practitioners in general practice are typically the first prescribers to diagnose and initiate pharmacotherapy for the treatment of obesity.[30]

Lastly, the general ST use of phentermine, as well as the fluctuations in the number of days it was supplied for, deserves discussion. As seen from Table 2, some patients received 30 mg phentermine for 1 day, while others received phentermine for 5, 7, 10, or 14 days. The relatively short DOT may be attributed to the 12-month study period and the use of the study's end date in its calculation. Additional contributing factors could include poor drug tolerability, financial constraints leading to intermittent collection by patients, or limited availability of the medication at pharmacies. Prescribers are advised to evaluate response to therapy only after a 4-week course of treatment.[15] However, as these numbers are only a reflection of the quantities dispensed and not the actual quantities prescribed, it is impossible to establish whether irrational drug prescribing occurred.

Study limitations

There were certain limitations to this study. First, the study population included patients who had approved and paid claims for phentermine, and excluded patients who had paid cash. Therefore, the number of patients receiving phentermine during the study

Table 1. Gender and age distribution of patients receiving 15 mg and 30 mg phentermine (*N*=3 361)

Characteristic	Total (*N*=3 361), *n* (%)	15 mg phentermine (*n*=1 419 (42.22%)), *n* (%)	30 mg phentermine (*n*=1 942 (57.78%)), *n* (%)
Female	2 848 (84.74)	1 224 (36.42)	1 624 (48.32)
Age group			
1	43 (1.28)	32 (0.95)	11 (0.33)
2	1 004 (29.87)	490 (14.58)	514 (15.29)
3	1 636 (48.68)	627 (18.66)	1 009 (30.02)
4	165 (4.91)	75 (2.23)	90 (2.68)
Male	513 (15.26)	195 (5.80)	318 (9.46)
Age group			
1	14 (0.42)	8 (0.24)	6 (0.18)
2	156 (4.64)	70 (2.08)	86 (2.56)
3	316 (9.40)	107 (3.18)	209 (6.22)
4	27 (0.80)	10 (0.30)	17 (0.50)

Age groups: 1 = ≤18 years; 2 = 19 - 34 years; 3 = 35 - 59 years; 4 = ≥60 years.

Table 2. Mean, minimum and maximum duration of therapy with phentermine for male and female patients by age group and prescriber

Variable	DOT, days, mean (SD)	Minimum DOT, days	Maximum DOT, days	*p*-value
15 mg phentermine	57.26 (58.72)	5	720	
Sex				0.0040
Female	58.55 (61.29)	5	720	
Male	49.15 (38.08)	5	330	
Age group				0.0004
1	62.25 (51.01)	30	210	
2	49.06 (43.78)	5	720	
3	62.70 (67.99)	7	720	
4	61.95 (56.30)	7	330	
Prescriber				0.8182
GP	57.07 (55.35)	5	720	
Specialist	58.31 (75.18)	7	720	
30 mg phentermine	67.10 (52.01)	1	360	
Sex				0.0291
Female	68.16 (52.74)	14	360	
Male	61.64 (47.79)	1	270	
Age group				
1	60.00 (76.49)	30	330	<0.0001
2	57.35 (40.00)	14	240	
3	71.46 (55.37)	1	360	
4	73.18 (60.03)	30	300	
Prescriber				0.0348
GP	67.80 (52.08)	10	360	
Specialist	58.59 (50.50)	1	330	

DOT = duration of therapy; SD = standard deviation; GP = general practitioner.
Age groups: 1 = ≤18 years; 2 = 19 - 34 years; 3 = 35 - 59 years; 4 = ≥60 years.

period could not be precise. Second, inaccuracy regarding the actual DOT with phentermine may have surfaced, since it was the dispensing information of the drug that was analysed, and not the actual consumption patterns. Finally, the DOT with the drug may have been miscalculated further, since the data were limited to the patients on the database for the specific study period, and clinical history and follow-up data were not available.

Conclusion

Phentermine is SA's most commonly prescribed oral appetite suppressant indicated for the ST management of obesity.[1,2,5,12,24] Current guidance limits its DOT to a period not longer than 12 consecutive weeks,[5] as ST use has been proven safe, effective and without severe side-effects.[1,2,4,5] Private sector data show that most prescriptions adhered to ST use (ST:LT = 3:1). However, phentermine was occasionally prescribed to individuals aged ≤12 years, as well as to the elderly, despite its use in such patients not being recommended.[5] Some of these individuals were also exposed to the potential adverse effects associated with LT therapy. These findings raise concerns about benefit-risk assessment and prescribing practices, warranting further investigation.

While phentermine dominates, other off-label weight-loss agents are also appearing on the market. Prescribers should be reminded to evaluate the risk ratios well, follow treatment recommendations and bear in mind age-appropriate use to ensure rational and safe obesity pharmacotherapy.

Data availability. The data used for this study are available from the authors on request.

Declaration. This publication is part of the requirements for AF's Master of Pharmacy degree at NWU.

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