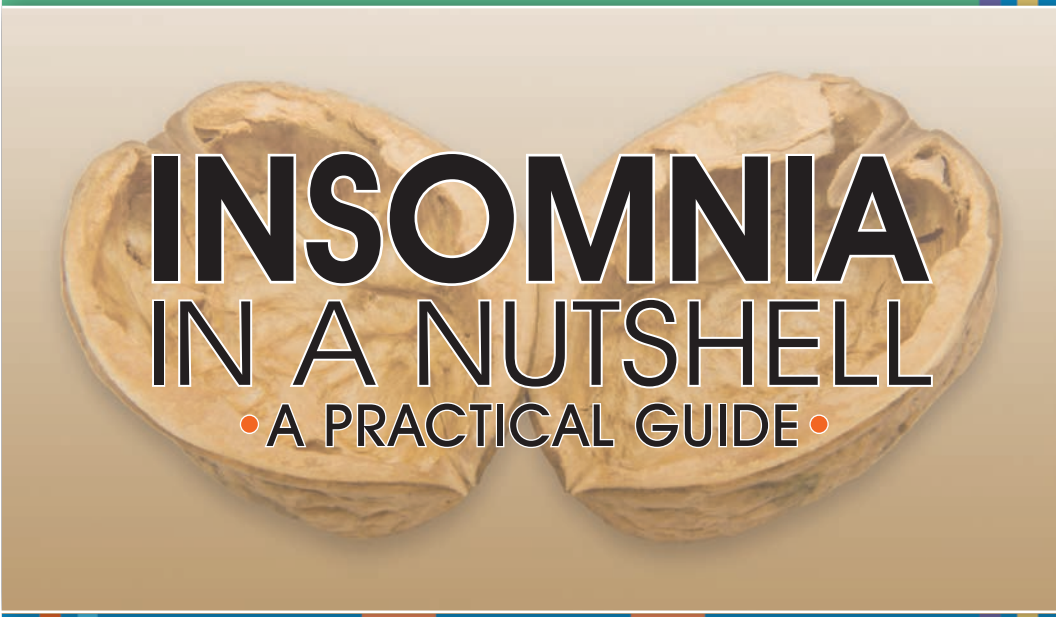

INSOMNIA IN A NUTSHELL

• A PRACTICAL GUIDE •

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Colin Shapiro has been involved in sleep research since 1972. After completing his medical degree in South Africa, he did a PhD in sleep physiology under the supervision of Professor Ian Oswald in Edinburgh. He subsequently trained in psychiatry and was a senior lecturer in the Department of Psychiatry in Edinburgh. At that time he established the British Sleep Society together with the now Sir Neil Douglas. He subsequently moved to Toronto where he became a full professor at the University of Toronto at the relatively young age of 37. He has been running sleep clinics in Ontario, Canada for almost 25 years.

A focus of Dr. Shapiro's interest has been the area of insomnia. He has published many studies on this subject but more importantly has treated hundreds of patients with severe insomnia, many of whom had been initially treated at other sleep clinics. His clinics have a broad-ranging program which includes the use of a wide-range of pharmacological as well as non-pharmacological approaches. In addition to running both short-term and long-term therapy groups, he employs specialists in his clinics who treat insomnia with alternative methods, such as meditation, acupuncture and art therapy. He has a strong liaison with the psychologist, Colleen Carney in the department of psychology at Ryerson University, who is a world authority in cognitive behaviour therapy for insomnia.

Dr. Shapiro has taken the opportunity to provide information and thoughts about his approach to the treatment of insomnia. Not all of these are the standard dogma but they are approaches that he has found useful in helping patients to recover from both short and long-term sleep problems.

He appreciates that the task of treating insomnia in a family practice setting is very different from that of a university hospital or small cottage hospital, which are locations in which he works. His late father was a family physician and in their discussions on insomnia it was often clear to Dr. Shapiro how much easier it was for him to treat insomnia compared to a family physician because of the resources at his disposal.

Shapiro says of this booklet: "I have tried to give both practical approaches and an understanding and rationale of why I think certain things work particularly well even if it is not considered the standard practice."

The comments made in this book reflect the opinion of the author.

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Index

Mission

Many physicians think of sleep difficulties they personally had as a student and don't appreciate the impact of chronic insomnia as it pertains to patients who have this as a night-after-night long-term experience. For patients who suffer from insomnia over a protracted period, the impact is profound. There are a range of strategies that can, and should be, used. Some of these are described in a book written for patients by six Canadian sleep specialists entitled "Insomnia in Adults and Children." This booklet provides a brief synopsis on insomnia for patients, and for parents of kids suffering from insomnia. It is a useful publication that can be left in your waiting room for patients to peruse. It can also be read on the website at: http://www.sleepontario.com/docs/INSOMNIA_BOOK_web.pdf

The current booklet is specifically aimed at giving primary-care clinicians a practical approach to dealing with insomnia.

A Brief Synopsis on the Management of Insomnia

I have received an unrestricted grant to provide family physicians, nurse practitioners and pharmacists with a brief synopsis on the management on insomnia.

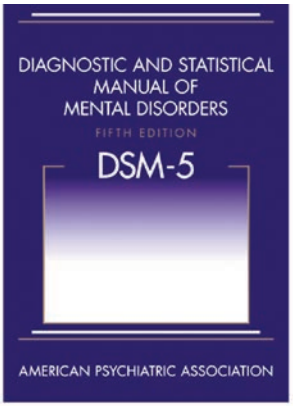
The reason for undertaking this exercise is that there has been a significant paradigm shift in this field. This relates to :

A) A NEW APPROACH REFLECTED IN DSM-V

B) BEST TREATMENT PRACTICE

C) DURATION OF TREATMENT

These three issues are all covered (albeit briefly) in this short booklet.



DSM-5 is the latest publication in the series

For several decades, insomnia has been seen as secondary to some other condition, for example anxiety or nocturnal asthma. It is now appreciated that, while insomnia may be the result of another condition, it is often a standalone affliction and needs to be treated in its own right.

In many conditions it can be considered as comorbid or a cause or trigger of another condition, for example, depression and hypertension.

"There is general agreement that when insomnia causes significant personal distress or marked impairment then some form of treatment is appropriate" (British Association for Pharmacology, consensus statement 2013.)

The NICE (National Institute for Clinical Excellence) Report

The best treatment practice is viewed by many as being **cognitive behavioural therapy for insomnia.**

For example, the NICE (National Institute for Clinical Excellence) report in the UK states that non-pharmacological interventions (for example, cognitive behavioural therapies) have also been shown to be effective in the management of persistent insomnia.

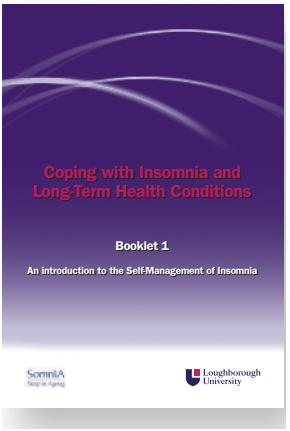
An American practice parameter's report of 2006 emphasizes that CBT for insomnia can be used in the acute situation for patients with chronic insomnia, in older individuals and in patients with chronic hypnotic use.

Insomnia is generally regarded as difficulty falling asleep, staying asleep or waking up early in the morning. In some definitions a feeling of being unrestored or un-refreshed following sleep is added. The latter is often the case when there are many brief arousals that the patient is not aware of. A complaint of fatigue rather than sleepiness is often the consequence.

Best treatment practice using the NICE pronouncement

Some years ago, a colleague, Kevin Morgan, who did his PhD in sleep alongside me in Edinburgh, Scotland, (in the early 1980s), approached funding agencies in the UK with the simple premise: there were about 12 million people taking hypnotics in the UK and only about 100 psychologists trained in cognitive behaviour therapy for insomnia. He received substantial support to develop what amounts to a simple "do-it-yourself" guide to psycho education.

Professor Morgan has been kind enough to provide the product of this endeavour to me and it is now on my website, http://sleepontario.com/login.php Feel free to view it there and to direct your patients to it. It is divided into six sessions, and patients can only go through the sessions at a rate of one per week



INSOMNIA leaflets

– akin to scheduling therapy. There is no charge for the use of this system where patients complete questionnaires and sleep diaries as they go through the process.

Approximately 70% of patients who go through a CBT-I program will benefit from it, and many will achieve a long-term change in their sleep. An American consensus statement regarding CBT-I states that **"CBT-I is as effective as short-term prescription medications are for the short-term treatments of "chronic insomnia".**

There is a sampler for physicians of this CBT-I program at the website, Each booklet created by Professor Morgan is amplified by three short video clips before the booklet and a clinical session after. There are further readings for each session in an information box. For your benefit a few tear-out referral sheets are provided at the end of this booklet (Pages 23 and 25.) If you need a full pad please email my secretary for a CBT referrals sheet at suzanne.alves@uhn.ca.

The above notwithstanding, many patients will still need hypnotic treatment. We sit at the crossroads of an exciting time in the development of new agents for sleep with three very different agents that have recently been, or are about to be, released.

One Shoe Does Not Fit All

There are many patients who have what I refer to as having "fragmented sleep", i.e. multiple brief arousals – often without the patient being aware of these arousals. Of course if there is a clear cause for these arousals, such as sleep apnea and the awakening associated with apnea events, then this underlying issue should be treated first. There may be general medical issues that need to be dealt with e.g. hyperthyroidism.

It should be noted that in large epidemiological studies it has been shown that patients who experience nocturnal awakenings, approximately 40% of them will wake up every night and the majority will have this problem for more than five years. This argues against a short-term fix (one to two weeks of hypnotic use which may be intermittent), and if hypnotics are needed this may well be for the medium-term (for example eight weeks of consistent use). The problem of nocturnal awakenings is especially common in the elderly, post-menopausal women and in those with medical conditions (especially heart disease, allergies, pain,

hypertension, GI reflux and obesity.) In some individuals who respond to medium-term use, there may be loss of effect following withdrawal. In these individuals a long-term plan needs to be formulated. This is discussed below.

These awakenings especially increase fatigue and cognitive difficulties (attention, memory, and concentration). There is evidence that only one third of patients who consult a GP regarding nocturnal awakenings receive any treatment!

There is the presumption that a medium-term hypnotic treatment does not lead to lasting improvement in sleep quality. There are studies (both recent and 30 years old) that show a lasting sleep improvement while hypnotics are being used. However the evidence of continued sleep benefit after cessation of medium-term (e.g. eight week program) hypnotic use is sparse. However, there is a widespread clinical impression that this does occur in many individuals. More research in this area is needed. For very different reasons, medium-term use of hypnotics is relatively unpopular with family physicians and with "ivory tower" specialists. The reasons are in part related to the anxiety about dependence.

A key statement in relation to tolerance, dependence and withdrawal of hypnotics is given by the British consensus statement of 2013 in which the authors write: "dose escalation above recommended doses in patients with insomnia is uncommon, and hypnotic drug effects are not a frequent problem in clinical experience; many patients use this same dose of hypnotic for months or years and still feel it works". In support of this, a 2008 paper by Andrew Krystal (of Duke University) and colleagues showed that there is sustained efficacy and safety (in a placebo-controlled trial) for six months with intermittent use of zolpidem 10 mg.

Research and clinical experience that shows that **withdrawal from the Z-drugs (zopiclone, zolpidem and zaleplon) is less problematic than withdrawal from benzodiazepines.** There is an early precedent of a six-month study showing effectiveness of benzodiazepines over the medium term, but with strong withdrawal effects at termination of benzodiazepine use. There are also eight-month and one-year studies showing lasting effectiveness of Z-drugs. It should be noted that zaleplon is available in Canada but currently only from compounding pharmacies.

Note:

By way of digression, sleep apnea, which in some cases causes sleep disruption and a form of insomnia in many sufferers, is only diagnosed in 5% of those who have the condition. Sleep apnea with insomnia is increasingly referred to as **"sleep apnea plus"**. Approximately 10% of your patients suffer from sleep apnea and under-diagnosis leads to significant morbidity, mortality and increased consumption of health resources. The diagnosis and treatment of sleep apnea may solve a proportion of insomnia problems. The following "STOP BANG" questionnaire is a quick and simple tool that will aid in the process of diagnosing sleep apnea. In any patient who scores 2 out of the 4 items in STOP, there is a 70% chance of apnea. Anyone who scores 3 out of the 8 items of STOP BANG there is also a 70% chance of apnea. In many hospitals STOP BANG has become a routine screening in the initial admission process of patients to hospital because of its high utility in detecting this significant disorder.

Some patients who appear to have insomnia may suffer from sleep apnea. Use the 45-second screening questionnaire on the next page and save lives!

This is particularly relevant as patients with treated sleep apnea have no particular risk when receiving a hypnotic medication. It should also be noted that the Z-drugs in general have essentially no respiratory depressant effects in marked contradistinction to benzodiazepines. Is it common-place for men in the American military who are prescribed CPAP to be concurrently given a Z-drug to help them in the early adaptation to using their CPAP.

STOP BANG

Do you **S**nore? Yes ❑ No ❑

Do you feel **T**ired, fatigued or sleepy during the day? Yes ❑ No ❑

Has anyone **O**bserved you stop breathing in your sleep? Yes ❑ No ❑

Do you have high blood **P**ressure? Yes ❑ No ❑

Please count the number of "Yes" responses and put the number in this box
There is a good chance that you have Sleep Apnea if you have two 'yes' responses out of four.

My neck size is _____cms_____inches

My height is _____cms_____inches

My weight is _____kgs_____lbs

B BMI > 35

A Age > 50

N Neck Size > 40cm > 15.7"

G Gender - Male

If height in ft	4'11"	5'0"	5'2"	5'4"	5'6"	5'8"	5'10"	6'0"	6'2"	
& weight in lbs is >	167	179	191	204	216	230	250	258	272	
If height in m	1.47	1.52	1.58	1.63	1.68	1.73	1.78	1.83	1.88	1.93
& weight in kgs is >	75	81	86	92	97	104	113	116	122	129

Then body mass index (BMI) kg/m² is > 35

If you count positive responses in STOP and BANG and three out of eight factors are applicable then you should have a sleep assessment.

The STOP BANG questionnaire is available at: http://www.sleepontario.com/docs/scales/STOP-BANG/STOPBANG_Illustrated_English.pdf For other sleep-related questionnaires available in more than twenty languages visit: http://www.sleepontario.com/services_scales.php

The Good, The Bad, and The Ugly (in Reverse Order)

The Ugly

To return to the issue of hypnotics, physicians have, to some extent, been led and misled by social and political forces into patterns of practice that seem to be somewhat nonsensical. This is ugly. There are treatments that are used (including long-term use) that are less desirable. This could be because of the side-effect profile of the agent; because of the lack of evidence of efficacy; or because of a lack of appreciation of potential long-term consequences. The following may be seen as a list of my "pet peeves" about agents that are used as hypnotics for which there should be significant concerns.

a) Trazodone: This antidepressant has become very widely used for some sleep promotion. The overwhelming evidence is that patients have a subjective sense of improved sleep but with very little objective evidence to substantiate this. The question that needs to be tackled is whether a subjective satisfaction is sufficient, or if it is a case of "a smoke and mirrors exercise" (distortion

of the truth), and in order to prevent the deleterious effects of poor quality sleep (including weight gain, poor daytime functioning etc.), a substantive change in sleep pattern is required in order to justify the use of this a medication for sleep.

b) Other antidepressants: Occasionally antidepressants are used primarily for their hypnotic effect. This stems out of a saga concerning triazolam in the late 1980s and early 1990s in which significant unreported side effects were shown. At that time doctors switched to older hypnotics e.g. Chloral hydrate and the use of antidepressants. This was on the basis that they were unlikely to be criticized for using low-dose antidepressants. In the situation where a depressed mood in a patient is seen to be a significant contributor to the insomnia, the use of a sedating antidepressant e.g. mirtazapine, is appropriate. In general it is better to prescribe mirtazapine at 7:00 p.m. as there is a slow-rise time to its sedating effect and this will help prevent people having morning-after somnolence.

Tricyclic antidepressants drugs, for example, amitriptyline, have significant side effects but are used because physicians are "less comfortable with hypnotics". However, the effects and side-effects of amitriptyline are more problematic than the realistic concerns about hypnotics.

c) Antipsychotics: This is in effect taking a "sledge hammer to crack a nut" with the possibility of long-term problems such as weight gain and long-term movement related problems. The use of low-dose quetiapine is a 'particular offender'. This may be because of the familiarity physicians have with using this drug but possibly have a lack of appreciation of the extent of the side effects. This is the veritable sledge-hammer to crack a nut.

Call a "spade a spade". If a patient needs a sleeping aid, choose the best there is - not a problematic substitute.

The Bad

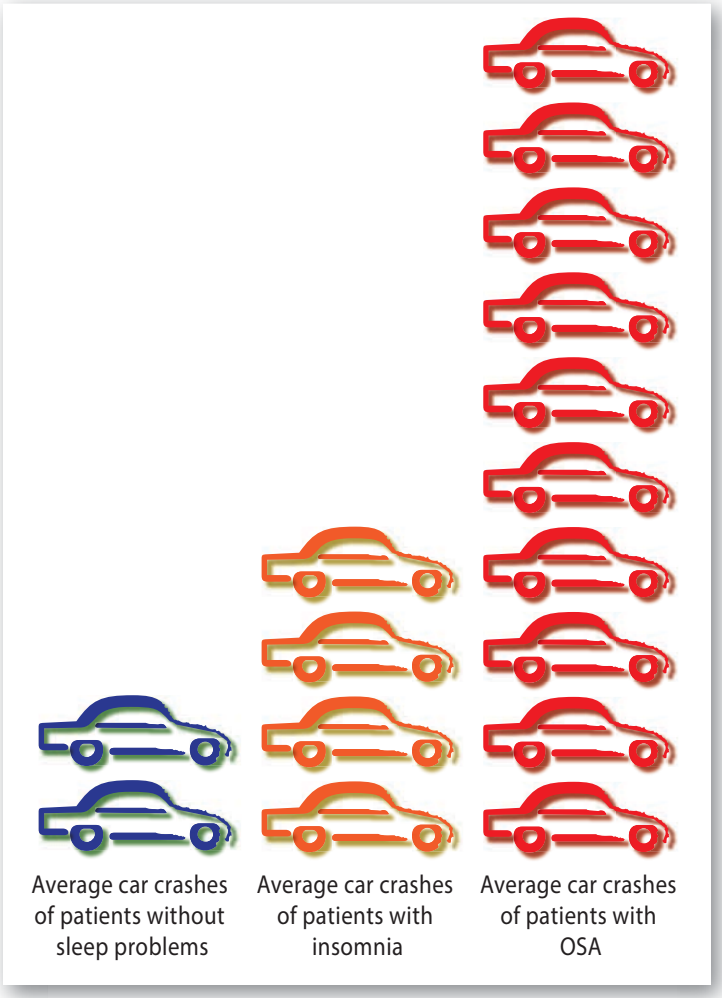
a) Melatonin: Although there is a lack of data in humans, melatonin has been shown to alter reproduction in animals. Recently it has been shown to cause early onset of puberty in girls. It is most unusual to have a hormone easily available over-the-counter. Melatonin is primarily a chronobiotic and has only a "10% hypnotic effect". There is some evidence that it works in the elderly who may have experienced "endopause", a term I coined to describe the decline of growth hormone secretion during deep sleep and the decline in melatonin secretion in some people over the age of 50. Melatonin is appropriate to use for jet lag and in other situations where there needs to be a shift in the body clock, e.g. phase delay syndrome. It is marketed for short-term use. The problem is that it soon delays bedtime (the chronobiotic effect) but the patient does not make the association.

However its use, especially in children, seems inappropriate unless there is clear evidence of an abnormal pattern of melatonin secretion such as in phase delay syndrome (which occurs in 7% of teenagers) or in children with fetal alcohol syndrome. The test that shows that there is a deficiency or inappropriate timing of release of this hormone is not widely available and is expensive at this time. It is not currently covered by provincial health insurances. For more information on the clinical use of melatonin please see: http://www.sleepontario.com/pamphlets/melatonin.pdf or http://www.sleepontario.com/services_dlmo.php

b) Antihistamines and over-the-counter agents: These generally have very brief longevity in terms of effectiveness. They can be helpful on an occasional basis but are not recommended. Some cause significant daytime impairment.

Use treatments that are shown to work: Melatonin is for body clock problems and antihistamines are for allergies. They are not surrogate sleep aids.

c) Homeopathic remedies: These are not study-based, and are not controlled by a governing body or a government health agency. However, there is no doubt that some of these agents do have relevant pharmacological effects. For example, St. John's Wort has some similar effects on sleep architecture as antidepressants – e.g. suppressing REM sleep (as shown in a study from Oxford University), however it is not a well-controlled substance.



Insomnia results in more car crashes!

The Good

There are a number of good agents available for sleep and doctors need to disabuse themselves of the notion that sleep-promoting agents are "bad". Like all medications, (e.g. antihypertensives and parkinsonian drugs), they need to be used when required and only for the duration they are required. This means acknowledging the serious consequences of insomnia such as increased car accidents in patients with insomnia compared to those without insomnia (see figure on opposite page).There is also an increased rate of depression among patients with insomnia and frequent relapse of depression after the occurrence of insomnia in a patient previously treated for depression. In general it is much more desirable for patients to have a short-term course of a hypnotic than a longer term re-treatment for depression. Finally, insomnia significantly impacts a person's quality of life.

A table of commonly and appropriately used hypnotic agents is provided on pages 12-13. Their benefits are highlighted in the clinical vignettes in the following few pages.

It should be noted that there has been evidence available for over two decades that post-benzodiazepine withdrawal results in cognitive problems. This is a debated issue.

In children, in particular melatonin can be substituted by ZZeeZZ-4-kidZZ (tryptophan.) ZZeeZZ-4-kidZZ is subject to quality control and is not an over-the-counter agent in Canada unlike melatonin. This is a bizarre anomaly; a food substance (amino acid) is on prescription but the hormone that is synthesized from tryptophan (melatonin), is not.

If there are significant sleep problems, then using a good hypnotic is appropriate.

TABLE OF SLEEP MEDI

	Name	Half-life	Dose (maximum / 24
Z Drugs	**Zolpidem (Sublinox)**	2-3 hours	5 mg (in women and the e 10 mg (in men) Note: In women can increase t
	Zopiclone (Imovane)	3.5-6.5 hours	5 mg, 7.5 mg (15 mg)
	Zaleplon	1-2 hours	10 mg
Benzodiazepines	**Temazepam (Restoril)**	8-10 hours	15 and 30 mg (60 mg)
	Lorazepam (Ativan)	9-16 hours	0.5, 1 and 2 mg (4 mg)
	Clonazepam (Rivotril)	18-50 hours	0.5 mg and 2 mg (8 mg)
Antidepre-ssants	**Mirtazapine (Remeron)**	20-24 hours	15 mg, 30 mg and 45mg
	Doxepine (Silenor)	15 hours	3 mg, 6mg
Other Agents	**Melatonin**	unknown	2 mg, 3mg 5 mg (6 mg)
	Tryptophan (Tryptan)	4-8 hours	750 mg (6000 mg)

The "Z" drugs are more specific and for many provide a better quality of sleep. They ar
They are easier to stop using and have less li

CATIONS AND EFFECTS

hours)	Drug interaction	Best used for
lderly) o 10 mg	chropromazine, fluconazole, imipramine, rifampicin, carbamazepine, phenytoin	initial insomnia
	carbamazepine, phenytoin, erythromycin, rifampicin, ketoconozole, imipramine	insomnia
	cimetidine, rifampicin, thiorizadine	middle-of-the- night insomnia
	CNS depressants	insomnia, muscle relaxant
	Divalproex, Phentoin, Theophilline, co- adminsitration of IM benzodiazepine and IM olanzapine	insomnia, anxiety disorder, seizure disorder
	CNS depressants, opioids, antihistamine, disulfiram, phenobarbital, phenytoin, carbamazepine, theophylline, rifampicin	insomnia, PLMS, status epilepticus, anxiety disorders parasomnia
	MAO Inhibitors, SSRIs (modest effect), Carbamazepine and Phenytoin	Anxiety Spectrum Disorders, Insomnia, Depression and Pain
	Monoamine oxidase inhibitors (MAOIs), antihistamines, C&S depressants, alcohol	maintenance insomnia
	unknown	circadian rhythm disorders
	vitamin B6, citalopram	insomnia, temperature sensitivity

e less likely to suppress REM sleep which plays an important roll in memory formation.
kelihood of dose escalation and dependence.

With regard to being at the cusp of a new wave of treatments, these can be summarized as follows:

New Wave:

1. **The advent of Sublinox (zolpidem) being available in Canada (in a 5mg or 10mg dosage) as a sublingual dissolvable tablet.**
2. **The recent marketing of Silenor (Doxepin HCl tablets) at 3mg and 6mg dosage.**
3. **The expected release of an Orexin antagonist.**

You will note that **Zolpidem** is both on the "good" and on the "new wave" list. The reason for this is that ironically this brand leader in the United States and many other countries known there as Ambien, (and available for over twenty years) was only recently introduced into Canada. The formulation (under tongue dissolvable) is new and has the advantage of quick onset but a full night effect.

Doxepine at low doses acts on different neurochemical components of the sleep-wake system. Specifically it has a very focused histaminergic effect rather than what is seen for the majority of agents being GABAergic. This may mean that for some individuals it will be a significantly better option as it attacks the problem from a different vantage point.

With regard to **Orexin antagonists**, this agent is possibly the first compound which, instead of enhancing sleep, will decrease wakefulness. For many individuals, the key issue causing insomnia is a hyper-arousal and this agent may be especially helpful in this population.

The concept that insomnia may be the "lack of sleepiness" or "an excess of wakefulness" was first proposed by my PhD supervisor, Ian Oswald in a paper almost 40 years ago entitled "Too much waking or not enough sleep." (British Journal of Psychiatry 1975, 126:439-45 (with Brezinova and Loudon.)

New agents with specific advantages will emerge and will need to be integrated into a comprehensive practice.

Duration of Treatment

"Insomnia is a long-term disorder".

"Many people have had insomnia for more than two years".
British consensus statement 2013.

There is no chronic condition for which the standard recommendation is a short-term treatment (compare with hypertension, asthma, Parkinson's disease or diabetes.)

Studies using databases with longitudinal information show that many patients going onto hypnotics end up taking hypnotics for a long period. There is a platitudinous moral rectitude that puts forward a case for using hypnotics for the shortest duration and only where needed. This would be akin to telling a patient: If you think your blood pressure will be up tomorrow take your antihypertensive today!

Chronic insomnia was shown in a Canadian study to be more common in women, older individuals and in patients with more severe insomnia at the outset. It would be wrong to discriminate against these groups.

If a long-term hypnotic treatment is likely to become more common or at least recognized, a more legitimate question for family doctors becomes: "How long are hypnotics useful for and when should the treatment be "paused" or "stopped?" An additional question would be: "Which drugs provide the best quality of sleep and are safe?"

Some view intermittent dosing as desirable. "Take it when you need it three to four times per week". The problem I see with this is that patients don't know in advance if they will be having a bad night and it places them in a quandary regarding what they should do on a particular night. It also ensures a Pavlovian conditioning paradigm as the night on which the hypnotic is used will almost invariably be associated with a subjective perception of better sleep. This means that the night without the hypnotic is worse and this sets up the model "sleeping pill – good, no sleeping pill – bad" which is exactly what one does not want to occur.

For this reason, I believe it is preferable to prescribe a course of treatment when using hypnotics. For both research and clinical reasons, I have found that eight weeks is an optimum time. This allows for a behavioural change to be made, a new pattern to be established and, I believe with the Z-drugs, a better quality of sleep to occur. I then ask patients to come off the medication for four weeks and to return for a follow-up appointment in 12 weeks after the prescription is given (i.e. eight weeks on the drug, four weeks off.) I warn of the potential of some withdrawal effects in the first one to two weeks after coming off the drug. The advantage of this formula is that with the impending clinical appointment, patients are prepared (and pleased) to stick with the plan. I use the analogy of fixing a broken

leg with a plaster cast ("your sleep is fragmented - it needs to join together and this will commonly take up to eight weeks. At the end of this you will remove the cast/sleeping pills but things may not be perfect for you to play football/sleep normally for the first week or two".) I do point out that for a majority this is true (but it also provides an element of therapeutic optimism.) There is the possibility that I am only providing the patients with a "walking stick", i.e. for some the hypnotic will be helpful only when they use it but as soon as they stop they will go back to "square one" and the drug no longer has an effect i.e. beyond the time used. This is not simply a withdrawal problem but an indication that this person "needs" a long-term hypnotic or a different plaster cast to obtain any lasting benefit. In the analogy, the walking stick does not allow the bone to knit. I always note that for a smaller percentage there may be no effect at all and a different approach may be required (for example insomnia as part of masked depression.) In summary, a two-month use of a hypnotic and a review after stopping for one month is a practical real-world strategy.

The following four clinical vignettes emphasize the diversity of treatment that is linked to insomnia. The vignettes have been chosen to emphasize a goal of treatment.

CLINICAL VIGNETTE 1

JD is a 64-year-old man with a number of stressors in his life. He has complained of sleep difficulties for over a decade and on two occasions had been referred to a sleep clinic and both clinics had commented that he had mild sleep apnea, one suggesting that he go on to CPAP and the other suggesting he does not. He had tried CPAP without any clear benefit. A third evaluation in our clinic showed minimal apnea and clear periodic leg movements in sleep. Treatment with an increasing dose of a benzodiazepine (clonazepam) yielded a dramatic improvement in his sleep. In the subsequent two years the patient - who had been struggling with his weight for many years - lost 46 lbs mainly by dieting and with minimal exercise. He attributed the weight change primarily to the improved quality of sleep, the reduction in tiredness and the enhanced ability to make better food choices.

Take home message: Treatment of insomnia can dramatically change quality of life. One needs to correctly identify the cause.

CLINICAL VIGNETTE 2

A nurse manager at a teaching hospital was diagnosed with maintenance insomnia. An eight-week group therapy for insomnia and a one-on-one cognitive behavioural therapy session yielded little improvement in her sleep. She was then prescribed zopiclone which she took on a daily basis for four years. After this period, she began to complain that while zopiclone at either the 5mg or the 7.5mg dose was effective, it left her with daytime fatigue. She was switched to zolpidem (sublinox) 10mg (the recommended dosage at the time she was seen) and immediately indicated that there was a dramatic improvement, her energy was better and her exercise tolerance, particularly in the morning, improved. She was also given the opportunity to participate in a mindfulness meditation program for insomnia which she found extremely helpful. On a scale from 0 – 100, she rated her sleep as 20 when first seen, 30 after the group therapy and cognitive therapy, 65 on the zopiclone and 90 after the meditation treatment and switching to sublinox.

Take home message: Finding the most appropriate medication and treatment for a patient with insomnia is not invariably a one-step exercise and may require a synergy between behavioural and pharmacological interventions.

CLINICAL VIGNETTE 3

A young, rather anxious, man complained of having tried "every psychological treatment for insomnia and all known medications other than antipsychotics". He stated, "my problem is not sleep – I am just wired all the time". He declined a meditation program and said that he had paid $1000+ for cognitive therapy. After hearing that there was a medication that may decrease wakefulness he agreed to try a low dose (6mg) of doxepin. After a month he described himself as "50% improved" and agreed to stop the drug and to go to the meditation program in our clinic. Two months later he felt that he was "75-80% improved" and said that he would follow up in a year.

Take Home Message: Some need to decrease wakefulness, others need to increase sleepiness.

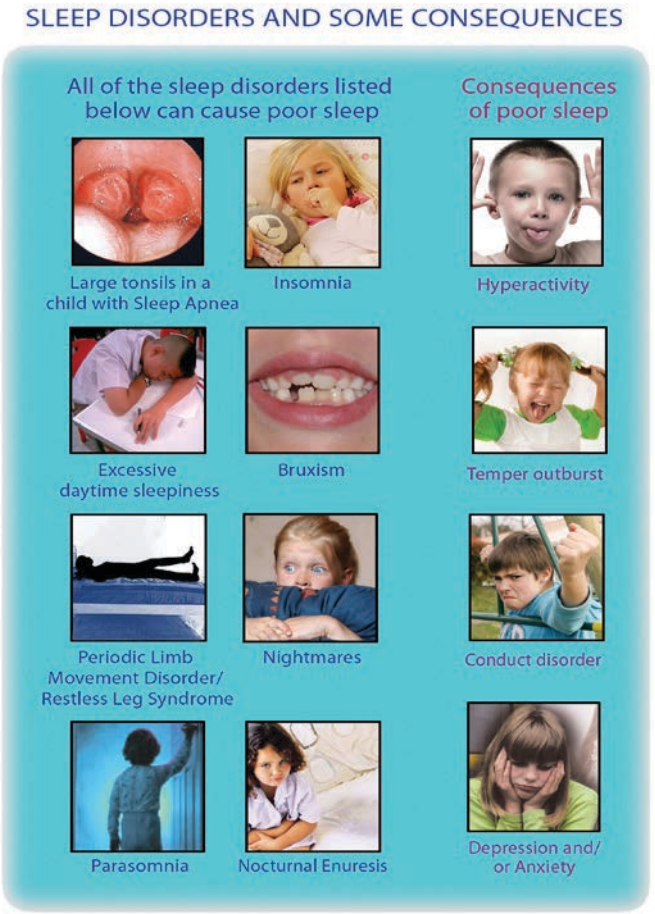
CLINICAL VIGNETTE 4

A slightly overweight 8-year-old was referred to the Youthdale Child and Adolescent Sleep Centre for assessment of his sleep complaints and ongoing enuresis. There was, in addition, a concern that he was grinding his teeth and would occasionally wake up and appear to spend long periods awake during the night. A sleep diary over a period of four weeks supported these observations and an actigraphic assessment showed a number of waking periods across the night. A formal sleep study was carried out which showed arousals from deep sleep with an increase of his heart rate (suggestive of parasomnia), without any evidence of epileptic phenomenon. In addition, there were repeated awakenings unrelated to any parasomniac activity. Behavioural counseling was provided but after two sessions his mother was frustrated at the lack of improvement and asked if there wasn't something more "concrete" that could be done. An increasing dose of tryptophan was prescribed using the regime of 750mg for two weeks - increasing by one tablet every two weeks to a maximum of six tablets. The caveat of excessive daytime sleepiness or nausea being reasons to dial back the dosage if necessary and the suggestion that the tryptophan be taken with a small amount of carbohydrate an hour before bedtime was emphasized.

After five weeks (and seven weeks prior to the planned follow-up appointment), the mother wrote a lengthy note to the clinic indicating a dramatic improvement in the number of awakenings and arousals during the night. (At this point the child was taking 2250mg of tryptophan.) At the 12-week follow-up visit the mother indicated that they had gone up to five tablets but as a result of slight nausea - and no further benefit as compared to when her son was on four tablets - they had gone back to four tablets and remained on that regime. She commented that the school had contacted her and had described a dramatic improvement in both the child's behaviour in general (less disruptive in class) and ability to concentrate during lessons. Attempts to withdraw the child from tryptophan in each of the following two summer vacations led to a return of some of the disrupted sleep behaviour (but not the enuresis) leading to reinstatement of the tryptophan. The third of these attempts showed no difference when tryptophan was withdrawn and the child thereafter remained off tryptophan. A follow-up a year later showed no requirement for any further intervention.

Take Home Message: The treatment of sleep problems in children can at times be managed with tryptophan which is infinitely more desirable than using a hormone such as melatonin and is more acceptable from the parent's perspective. Information about tryptophan use can be found at: http://www.sleepontario.com/pamphlets/tryptophan.pdf

The following graphic indicates changing the sleep of children can make a very large impact on the child's function and well-being. (From *Insomnia in Adults and Children* available at: http://www.sleepontario.com/docs/INSOMNIA_BOOK_web.pdf)



The Questionable

There is sparse evidence that marijuana promotes sleep. The effect is variable and may depend on the source and composition of the marijuana vis-à-vis the range of the THC's (Tetrahydrocannabinols) in the marijuana. There are usually over 60 THC's in marijuana that is smoked. This seems too uncertain in terms of variability of effect (sometimes sleep-promoting, sometimes causing arousal) for a physician to recommend. However medical marijuana which has only one THC, for example cesamet, may find a place in treatment-resistant patients.

DIFFERENCES BETWEEN TW

The following table (based on recent publications), emphasizes the contrast betw
the past 20 years and **Zopiclone (Imovane)** which has been the brand leader in C
alternative was simply not available but now both are available in both countries
little hangover likelihood, low abuse potential, good sleep continuity, low risk of fo
one would hope that the sleep architecture remains normal which would decrea
and a minimum of adverse effects.

IDEAL HYPNOTIC	ZOLP (SUBL
Quick onset	+ Better sleep ons
No hangover	+ Less day-after ef e.g. no sleepines
No side effects	– Less efficient on
Easy to withdraw	+ Less rebound ins
Good quality sleep	Acts on alpha-1 subty (more in t
Specific action on sleep, i.e. not anxiety, etc.	Half-life abo
No rapid withdrawal effect	
Good daytime function	+ Both protect sleep arc
Long-term lasting effects	

** This is also a distinct advantage vis-a-vis cognitive function in the elderly i*

VO LEADING HYPNOTICS

een **Zolpidem (Sublinox)** which has been the "brand leader" in the USA for anada for a similar period. In both countries for most of this period, the other , albeit in a different form. The ideal hypnotic is one that has a quick onset, alls as a consequence of the drug or of respiratory suppression. Furthermore ase the likelihood of rebound insomnia and there should be an ease of use

IDEM LINOX)		ZOPICLONE (IMOVANE)
et	–	Less rapid sleep onset
ffects * s while driving	–	More day-after effects e.g. possible sleepiness while driving
end of night awakenings	+	Better for end of night awakenings
somnia	–	More rebound insomnia
FACTUAL		
ype of GABA receptors he cortex)		Acts on alpha-3 receptors (more in the reticular nucleus)
ut two hours		Half-life about five hours
COMMON FINDINGS FOR BOTH MEDICATIONS		
+ Both improve sleep continuity		
+ Daytime mood improved similarly		
chitecture compared to benzodiazepines and antidepressants i.e. better sleep quality		
+ Both can be lastingly effective		
+ Both have little tendency for dose escalation		
+ Similar levels of complex sleep behaviours		

n particular. (this is probably because of the lower alpha-5 receptor activity).

Conclusion

After a famine of almost twenty years without significant new treatments for insomnia in Canada, we have several new approaches that have come on-line i.e. one might say the nutshell is cracked. This applies to both pharmacological and behavioural treatments.

Cognitive behaviour therapy for insomnia works but is less readily available and under-utilized. I hope that the "coupons" at the end of the book addresses this issue to some extent (please feel free to photocopy these coupons and give them to patients.)

Some of the recommendations in this booklet, for example regarding longer use of hypnotics if needed are not widely accepted as standard practice. It is based on a balance sheet of risks and harms, a real-world experience of treating many patients and the appreciation that if one matches the patient and the medication the likelihood of escalating dosage and true dependence is very small.

Finally, the best bet for real improvement is **sleep quality** as well as quantity and improved daytime functioning with the judicious use of a Z-drug can occur in today's world i.e. with the treatments currently available.

Best Wishes,

Colin Shapiro

A number of references of relevance can be found on the website:
www.sleepontario.com

I thank the three companies, Valeant, Merck and Paladin that have made it possible for me to provide the cognitive behaviour therapy for Insomnia on our website.

You can find a cognitive behaviour therapy for insomnia program on the website: http://sleepontario.com/login.php There is no charge for this program. There is also a book entitled "Insomnia in Adults and Children" on this site listed under "Publications"

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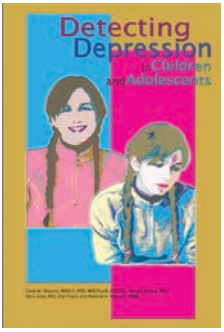

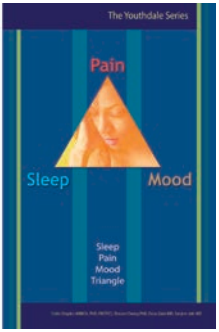

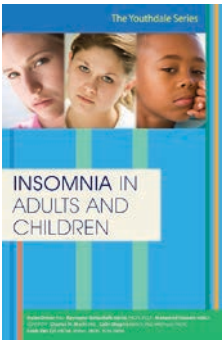

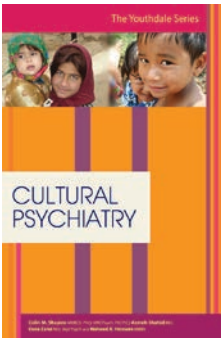

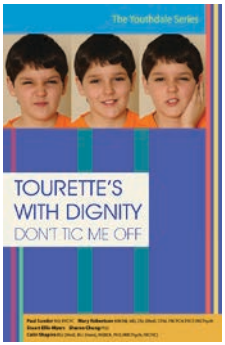

Other booklets that are available on the website: www.sleepontario.com

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