Volume 15 Issue 2 / Fall - Winter 2012

The Renal Pharmacist

Vol 15

Issue 2

Fall - Winter 2012

In this issue ...

A biannual Insight into the Renal Pharmacist Network

View from the Chair

Change is good. It's that time of year once again when the torch is passed. The RPN has matured and is now a young adult. Not surprising that it wants to take a breath of fresh air and see new horizons. But what is this metaphor? In the past year the RPN has established itself on solid grounds for years to come. The executive committee has done the necessary work to have the RPN recognized as an official not-for-profit organization (NPO) to ensure its' legal and financial obligations.

As with many young adults, the Newsletter also got a new look and a French version of the Newsletter is now available for our Quebec colleagues. The RPN has also contracted a new website maintenance provider, which will make additions and modifications to the website much easier and less expensive. Finally, it was time to change our banking partners, to ensure that our treasurer has all the support needed so that transactions can be made efficiently in a timely fashion. All in all, a great year of changes for the RPN in terms of structuring the operational aspects of our network. The annual educational day and the CE events held in Toronto, Winnipeg and Vancouver were of outstanding quality and well attended. I am reaching out to all RPN members to consider attending the CSN-RPN meeting that will be held in Montreal April 2013, which will certainly be a historic pan-Canadian nephrology get together. Be there.

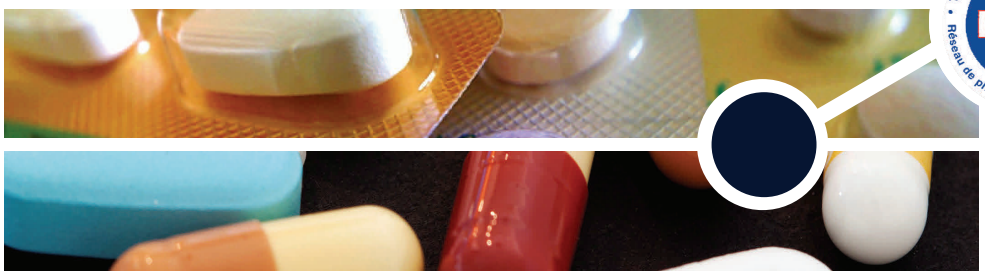
"Change is good"

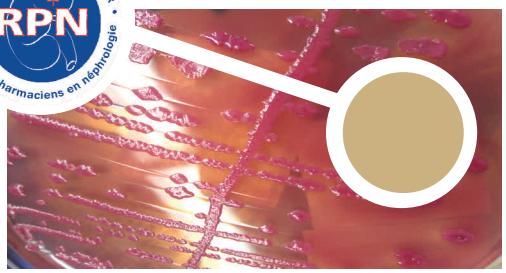
In these last few words as chair of the RPN, I wish to give a very special thank you to all the members of the RPN executive committee for their outstanding support and devotion for making the RPN what it is today. Thank you, Marisa, Judith, Amy, Grace, Elaine, Piera and Jenny. My wish for the next year, is to have some representation from the Maritimes so that the RPN becomes a truly national, coast–to-coast Renal Pharmacist Network. As chair elect you will be supported by a group of seasoned renal pharmacists who will guide you, without pain, into a well groomed organization. This would really be quite a change for the RPN. As I already mentioned... change is good!

Sincere seasons greetings to everyone,

Robert Bell

Chair of the RPN





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www.renalpharmacists.net

Upcoming Conferences

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National Kidney Foundation 2013 Spring Clinical Meetings is scheduled April 2-6, 2013 in Orlando, Florida.

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Canadian Society of Nephrology (CSN) 2013 is scheduled **April 24-28, 2013** in Montreal, Quebec. The RPN will be holding a joint education day prior to meeting so please plan to attend! More information to follow at a later date.

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American Society of Nephrology Kidney Week 2013 is scheduled for Nov 5-10, 2013 in Atlanta, Georgia.

Canadian Society of Nephrology

Apply for Pharmacist Membership to the Canadian Society of Nephrology!

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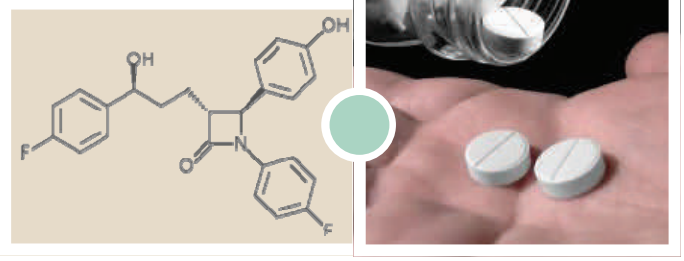
Highlights: RPN Winnipeg Continuing Education Evening 2012

Submitted by Amy Sood, BScPhm, PharmD, St. Boniface Hospital, Winnipeg, MB

The RPN hosted a Winnipeg Continuing Education Evening on November 28, 2012. There were nearly 20 attendees at this event, including a good representation of renal pharmacists from our 3 hospital sites in Winnipeg. Dr Krista Ryz was invited to speak on "Statin therapy in CKD & ESRD: Revisiting an old controversy in light of the SHARP trial". In this presentation, Dr. Ryz highlighted the significance of cardiovascular disease and how it differs from the general population. She also reviewed the rationale and evidence for statin therapy in CKD and finally, critically appraised the SHARP trial. This is timely as KDIGO will be publishing its new lipid guidelines in February 2013. We got a sneak peak of these guidelines at the ASN in San Diego and it promises to be practice changing. There was lots of discussion afterwards on how to deal with secondary prevention. For example, do we need to intervene on our hemodialysis patients with acute myocardial infarction started on atorvastatin 80 mg/day? Though there were more questions than answers, it was a good opportunity to re-examine the evidence and network with our colleagues. Thanks to the sponsors who attended the event and all the sponsors who support the RPN for making this evening possible.



Highlights: RPN Toronto Continuing Education Evening 2012

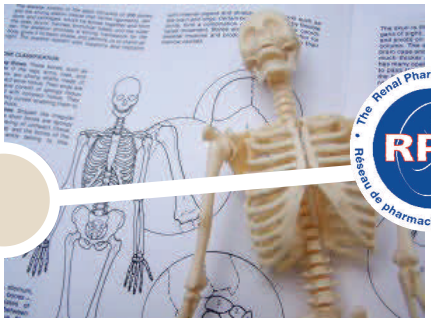
Submitted by Jenny Ng, BScPhm, Sunnybrook Health Sciences Centre, Toronto, ON.

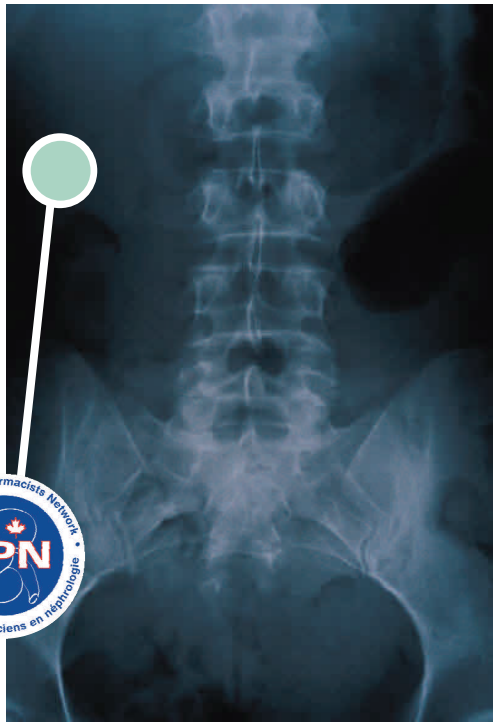
On November 21st, Dr. Sophie Jamal presented to the renal pharmacists of the greater Toronto area on the topic of treatment of osteoporosis in chronic kidney disease (CKD).

She shared her knowledge with us on increased fracture risk and bone disease in people with chronic kidney disease. Dr. Jamal detailed some of the challenges/limitations of bone assessment in patients with kidney disease. Bone mineral density (BMD) is traditionally used for osteoporosis assessment, however, BMD of hip and spine are poor discriminators of fracture status in stage 5 CKD. One alternative that may be useful in fracture assessment is muscle strength testing. It is easy and inexpensive to implement and is a good discriminator in fracture status in early and late CKD.

Dr. Jamal reviewed the data or lack there of for treatment options such as bisphosphonates, denosumab, raloxifene, vitamin D, calcimimetics, and teriperitide in stages 2-5 CKD (*Refer to slides on renal pharmacists network website*). She did highlight that careful monitoring for hypocalcemia is required when using denosumab especially in those that are already vitamin D deficient.

It was an great opportunity for renal pharmacists to get together and learn some practical tips on management of bone disease in people with kidney disease.





Highlights: RPN Vancouver Continuing Education Evening 2012

Submitted by Judith Marin, B.Pharm, M.Sc., PharmD, Fraser Health Authority Renal Program, Surrey, BC

On November 15th, the RPN hosted a Continuing Education Event at the Vancouver Italian Cultural Centre. Our members had the pleasure of attending two great presentations. First, Dr. Marianna Leung discussed how to improve dialysis patients' quality of life by familiarizing us with symptoms management. She presented some treatment algorithms now posted on the British Columbia Provincial Renal Agency (BCPRA) website. The second talk by Naomi Taylor on nutrition and chronic kidney disease, was also well received. Naomi reviewed renal diet restrictions with the group and gave examples to illustrate how they affect eating habits. Both presentations are summarized in detail in this RPN Newsletter issue. Once again, our continuing education evening was a success with the opportunity to discuss and share ideas with our colleagues.

Naomi Taylor, RPN Vancouver Continuing Education Evening 2012.

Participants at the RPN Vancouver Continuing Education Evening 2012.

The **Renal Pharmacist Network** is looking for a **Chair-Elect for 2013**!

Why not get involved with your renal colleagues across Canada and join our group. It is a 3 year term (Chair-Elect 2013, Chair 2014, Past Chair 2015) and will promise to be a rewarding experience.

If you would like more information about getting involved, please email Piera Calissi at Piera.Calissi@interiorhealth.ca

Insomnia Treatment Algorithm for Hemodialysis Patients *Supplemental Summary*

Submitted by Marianna Leung, PharmD, BCPS, BCPP, CDE, FCSHP, Clinical Pharmacy Specialist, St. Paul's Hospital, Providence Health Care, Vancouver, BC . Acknowledgments: BCPRA (British Columbia Provincial Renal Agency).

Chronic insomnia in hemodialysis patients are common and likely multifactorial. It is prudent to identify and minimize contributing factors, if feasible.

There are increasing evidence supporting the effectiveness of both non-pharmacologic and pharmacologic therapies for insomnia; however, the literature is lacking in patients with chronic kidney disease (CKD) and therefore, treatment recommendations are extrapolated from the general population. In addition, most studies assess short-term treatment of insomnia and not the chronic issue faced by CKD patients.

In terms of non-pharmacological therapies, good sleep hygiene is strongly encouraged. Compliance with sleep hygiene is usually poor; hence, it is important for patients to understand that successful treatment is only possible if they are willing to change ingrained bad habits. Cognitive

behavioral therapy, relaxation techniques, or structured exercise programs should also be considered either before or concurrently with pharmacological treatment.

Medication is mostly indicated for transient insomnia and should be reassessed after 2 to 4 weeks with the goal of minimizing its use.

Medications to avoid:

Antihistamines (over-the-counter), e.g. diphenhydramine – due to their adverse effects (anticholingeric, dizziness), residual daytime sedation, and high risk of tolerance.

Antipsychotics (sedating), e.g. quetiapine, olanzapine, methotrimeprazine – due to their risk of tardive dyskinesia and anticholinergic or orthostatic hypotensive adverse effects (for traditional antipsychotics)

Benzodiazepines- long acting, e.g. flurazepam, chlordiazepoxide or diazepam – due to their residual effects (sedation, impaired cognitive and psychomotor function)

Benzodiazepines- short acting, e.g. triazolam – due to the risk of antegrade amnesia, rebound insomnia or daytime anxiety.

Chloral hydrate – contraindicated in patients with severe renal impairment; risk of overdose due to its low therapeutic index.

L-tryptophan –data on the efficacy and safety of this medication is lacking. Also, combination with other serotonergic medications, e.g. SSRIs, SNRIs, may lead to serotonergic syndrome.

Tricyclic antidepressants, e.g. amitriptyline – due to their adverse effects (anticholinergic, cardiovascular)

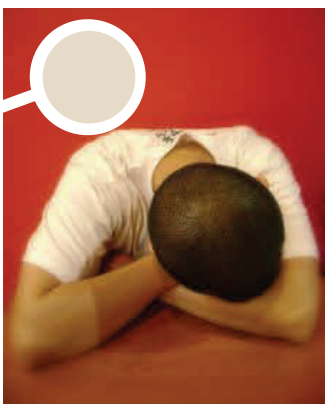
Evidence:

Only 2 hypnotic studies were conducted in hemodialysis patients. One randomized, double-blind, placebo-controlled, crossover study[1] compared zaleplon 10mg PO HS (or 5mg if age > 65 years) vs placebo x 15 days in 10 hemodialysis patients with insomnia. Zaleplon was found to improve subjective sleep quality and a reduced sleep latency from 35 to17.6 minutes ($p<0.01$).

The other randomized, double-blind, placebo controlled, crossover study[2] involved melatonin 3mg vs placebo PO HS x 6 weeks in 20 patients. Patients reported reduced sleep latency from 44.5 to 15.5 minutes ($p=0.002$) and improved sleep efficiency from 67.3% to 73.1% ($p=0.01$) after melatonin treatment.

Study References:

1. Sabbatini M, Crispo A, Pisani A, et al. Zaleplon improves sleep quality in maintenance hemodialysis patients. Nephron Clin Pract 2003;94:c99-103.
2. Koch BC, Nagtegaal JE, Hagen EC, et al. The effects of melatonin on sleep-wake rhythm of daytime haemodialysis patients: a randomized, placebo-controlled, crossover study (EMSCAP). Br J Clin Pharmacol 2009;67 (1):68-75.



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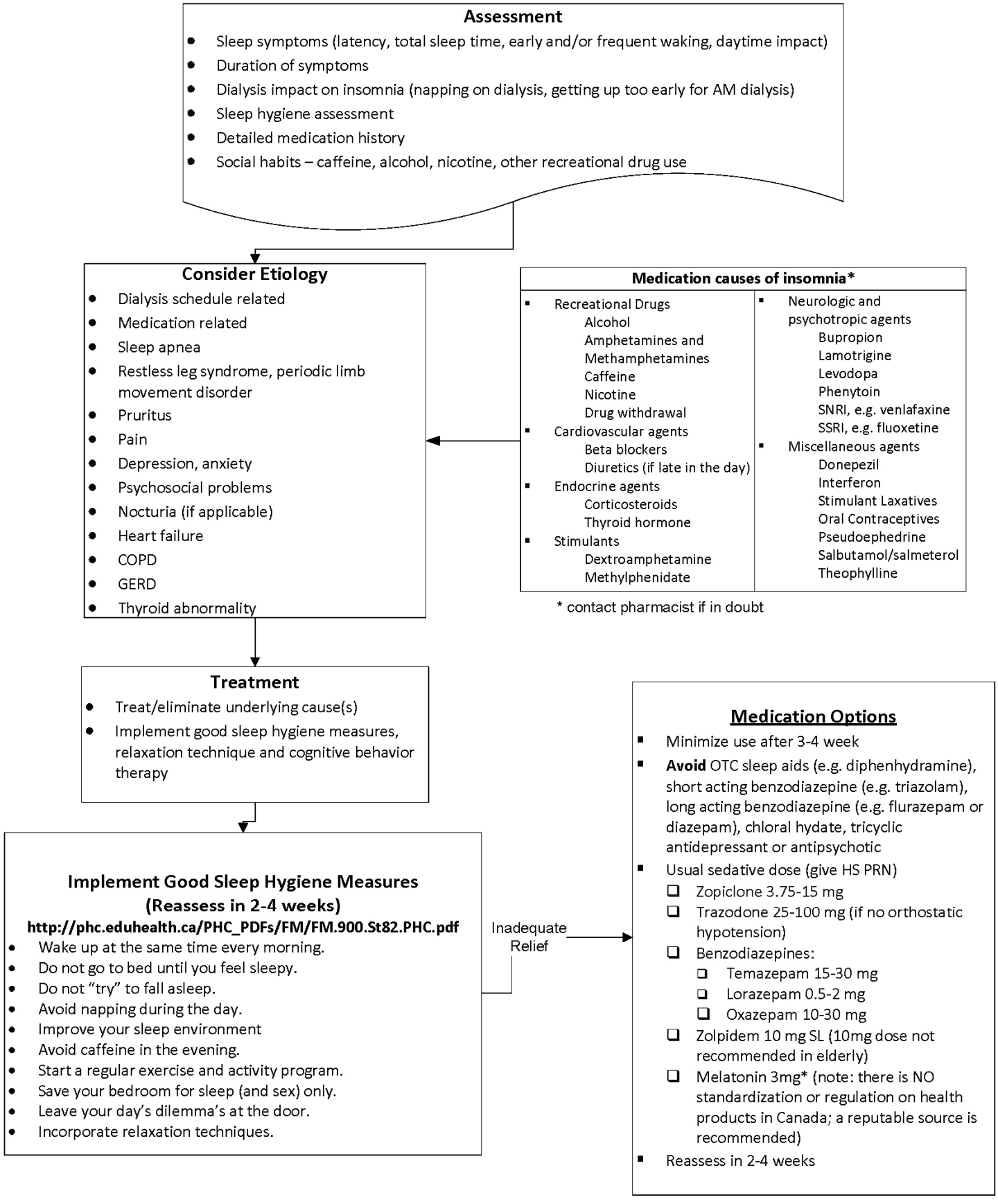
Insomnia Treatment Algorithm for Hemodialysis Patients

Draft September 21, 2012



Submitted by Marianna Leung, PharmD, BCPS, BCPP, CDE, FCSHP, Clinical Pharmacy Specialist, St. Paul's Hospital, Providence Health Care, Vancouver, BC. ***Acknowledgments: BCPRA (British Columbia Provincial Renal Agency).***

Pruritus Treatment Algorithm for Hemodialysis Patients *Supplemental Summary for Treatment Options*

Submitted by Marianna Leung, PharmD, BCPS, BCPP, CDE, FCSHP, Clinical Pharmacy Specialist, St. Paul's Hospital, Providence Health Care, Vancouver, BC . *Acknowledgments: BCPRA (British Columbia Provincial Renal Agency).*

In terms of non-pharmacological therapies, moisturizing cream should be considered for all hemodialysis patients as xerosis is prevalent in this population. Lotions are not recommended since the higher concentrations of emulsifiers and stabilizers and the lower concentration of lipid in lotions can further worsen the dry skin. Other non-drug measures, e.g. minimizing the use of soap and hot bath, should also be considered. The successful use of behavioral therapy or habit reversal techniques has been reported in patients with chronic pruritus; however, their utility in the hemodialysis population has not been studied. A dermatology consult should be considered early for other differential diagnosis or UVB phototherapy in severe or difficult-to-treat cases.

In terms of pharmacotherapies, available literature in hemodialysis patients is limited. Most studies are of small sample size, from single centre, have significant drop-outs or crossover design with a short washout period.

Although there are no studies confirming the efficacy of sedating antihistamines in the treatment of pruritus in hemodialysis patients, they have historically been used as first line agents for this indication. Non-sedating antihistamines have not been shown and are not considered to be effective by experts in alleviating pruritus in hemodialysis patients as they do not cross the blood brain barrier, and therefore unable to affect the perception of itch. Due to the lack of confirmatory studies, the agents listed under limited evidence are not included in the treatment algorithm but could be considered if other typical more cost-effective agents fail.

Positive Studies:

Capsaicin (topical)

In a double-blind, placebo-controlled, crossover trial[1] of 34 hemodialysis patients with uremic pruritus, capsaicin 0.03% was compared to placebo x 4 weeks with a 2-week washout. The mean pruritus score (maximum 18 points) was significantly reduced from 15.9 + 6.3 to 2.5 + 2.5 in the capsaicin treatment period vs 15 + 6.0 to 7.2 + 5.5 in the placebo treatment period.

In another double-blind, placebo-controlled, crossover study[2], capsaicin 0.025% cream was compared to placebo in 17 hemodialysis patients with moderate to severe pruritus. Fourteen had marked relief, of whom 5 had complete remission, with prolonged antipruritic effect 8 weeks post capsaicin treatment. No serious adverse reactions were noted.

In an open-label uncontrolled trial and a double-blind, vehicle-controlled trial[3] evaluating capsaicin 0.025% cream in hemodialysis patients. Eight of 9 evaluable patients in the open label trials reported marked relief or complete resolution; 12 patients were not evaluable. In the double-blind trial, 2 of 5 evaluable patients reported

complete resolution and 2 were not evaluable. No serious adverse reactions were noted.

Doxepin

In a randomized, placebo-controlled, crossover trial[4], doxepin 10mg po BID x 1 week was compared to placebo in 24 patients with pruritus resistant to conventional treatment. There was a 1-week washout between treatment periods. Mean age was 48 years. Complete resolution was reported in 58.3% patients with doxepin vs 8.3% with placebo ($p<0.001$) with relative improvement in 29.2% vs 16.7%, respectively. Drowsiness was reported in 50% of patients, which resolved in about 2 days. One patient refused doxepin.

Although there is only one study conducted with doxepin in the treatment of pruritus in hemodialysis patients, it has been successfully used in the treatment of intractable pruritus due to its strong anti-H_1 histaminic activity. If there is no contraindication to tricyclic antidepressants, doxepin

may be tried after topical capsaicin and/or gabapentin.

Gabapentin

In a double-blind, placebo-controlled, crossover trial of 34 hemodialysis patients who failed antihistamines and moisturizers[5], gabapentin 100mg po 3 times weekly post-hemodialysis x 4 weeks was compared to placebo with a one-week washout. Out of a maximum of 100 points, the mean pruritus scores were 6.44 + 8.4 during gabapentin vs 81.11 + 11.07 during placebo period (p<0.001). Dizziness, drowsiness and fatigue were reported in 2 patients.

In a randomized, double-blind, placebo-controlled trial[6], 34 hemodialysis patients were assigned either gabapentin 400mg po twice weekly post-HD vs placebo x 4 weeks. On a 10-cm visual analogue scale, the mean reduction in pruritus score was 6.7 + 2.6 vs 1.5 + 1.8 in gabapentin vs placebo groups, respectively (p<0.001). No drop outs due to side effects.

In an open-label series[7], 5 consecutive HD patients unresponsive to antihistamines received gabapentin 100mg po 3 times weekly post-HD with dosage adjusted to clinical response. The mean visual analogue scale decreased from 8.4 to 1.6. Two patients received complete itch remission.

In another randomized, double-blind, placebo-controlled, crossover study[8], gabapentin 300mg po thrice weekly post-HD was compared to placebo x 4 weeks with a one-week washout in 25 patients who failed conventional therapy. The mean pruritus score reduced from 8.4 + 0.94 to 1.2 + 1.8 for gabapentin (p=0.0001) and to 7.6 + 2.6 for placebo (p=0.098). Mild to moderate somnolence, dizziness and fatigue were reported.

Limited evidence:

Activated Charcoal

In an open-label case series[9], 23 hemodialysis patients were treated with activated charcoal 6g po daily (30 x 200mg capsules) x 6 weeks. Ten single -blinded patients received placebo treatment prior to charcoal. Ten patients' pruritus completely resolved, 10 had partial response while 3 were unresponsive. Four patients complained of nausea, weight gain or difficulty with pill burden.

In a double-blind, placebo controlled, crossover study[10], activated charcoal 6g po daily x 8 weeks was shown to relieve pruritus in 10/11 hemodialysis patients with idiopathic generalized pruritus (p=0.01). Four patients were non-compliant. No adverse effects were noted.

Although there is some limited evidence suggesting the efficacy of activated charcoal, the product is commercially available as 260mg capsules and may be compounded as 360mg capsules by compounding pharmacies. Therefore, it requires 17 to 23 capsules per day to make up a 6g daily dose. In addition, activated charcoal may bind to and needs to be spaced apart from other medications during administration. Due to the significant pill burden and potential drug interactions, this option is not listed in the algorithm but may be used as a last resort.

Gamma-linolenic acid (topical)

A randomized, double-blind, placebo-controlled, crossover study[11] compared gamma-linolenic acid 2.2% cream vs placebo for 2 weeks with a 2-week washout in 16 dialysis patients with refractory uremic pruritus. Gamma-linolenic acid cream shows statistically significant change in visual analogue scale and pruritus score compared to placebo.

Montelukast

In a randomized, single-blind, placebo-controlled, crossover study[12] in 5 hemodialysis centers, 16 patients were treated with montelukast 10mg po daily x 20 days vs placebo with a 14-day washout. Pruritus was reduced by 35% (95% CI, 9.5% to 62.5%) with montelukast vs 7% (95% CI, 0.5% to 15.9%) with placebo (p=0.002).

Pregabalin

An open-label series[13] evaluated pregabalin 25mg po HS in 16 hemodialysis patients refractory to antihistamine for 2 months (hydroxyzine or desloratadine + levocetirizine). There was a statistically significant difference between the 10-point visual analogue scores before and one month after treatment, 7.44 + 2.01 vs 1.7 + 1.31, respectively. Four patients discontinued treatment due to side effects.

Negative Studies:

Naltrexone

A randomized, double-blind, placebo-controlled, crossover study[14] compared naltrexone 50mg po daiy x 4 weeks vs placebo in 23 hemodialysis and peritoneal dialysis patients with persistent, treatment resistant pruritus. Seven patients did not complete the

study. No statistically significant difference was found between the naltrexone and placebo treatment periods.

A randomized, double-blind, placebo-controlled, crossover trial[15] found naltrexone 50mg po daily x 7 days to be effective in 15 hemodialysis patients with severe resistant pruritus. The

median pruritus scores were reduced from 9.9 (out of 10) to 2.1 for the naltrexone-placebo sequence and 1.0 for the placebo-naltrexone sequence at the end of the naltrexone treatment. Short term efficacy was shown in this study.

Ondansetron

A randomized, double-blind, placebo-controlled study[16] failed to demonstrate ondansetron 8mg po TID x 2 weeks to be more effective than placebo in 24 hemodialysis patients.

A prospective, placebo-controlled, double-blind, crossover study[17] compared ondansetron 8mg po TID vs placebo x 2 weeks in 16 hemodialysis patients with persistent pruritus. No statistically significant difference in daily pruritus score was reported between both treatment periods.

Tacrolimus 0.1% Ointment

A randomized, double-blind, vehicle-controlled study[18] failed to demonstrate tacrolimus 0.1% ointment (n=12) to be more effective than vehicle (n=8) in relieving uremic pruritus.

Study References:

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18. Duque MI, Yosipovich G, Fleischer AB Jr, et al. Lack of efficacy of tacrolimus ointment 0.1% for treatment of hemodialysis-related pruritus: a randomized, double-blind, vehicle-controlled study. J Am Acad Dermatol 2005;52(3 Pt 1):519-21.

General References:

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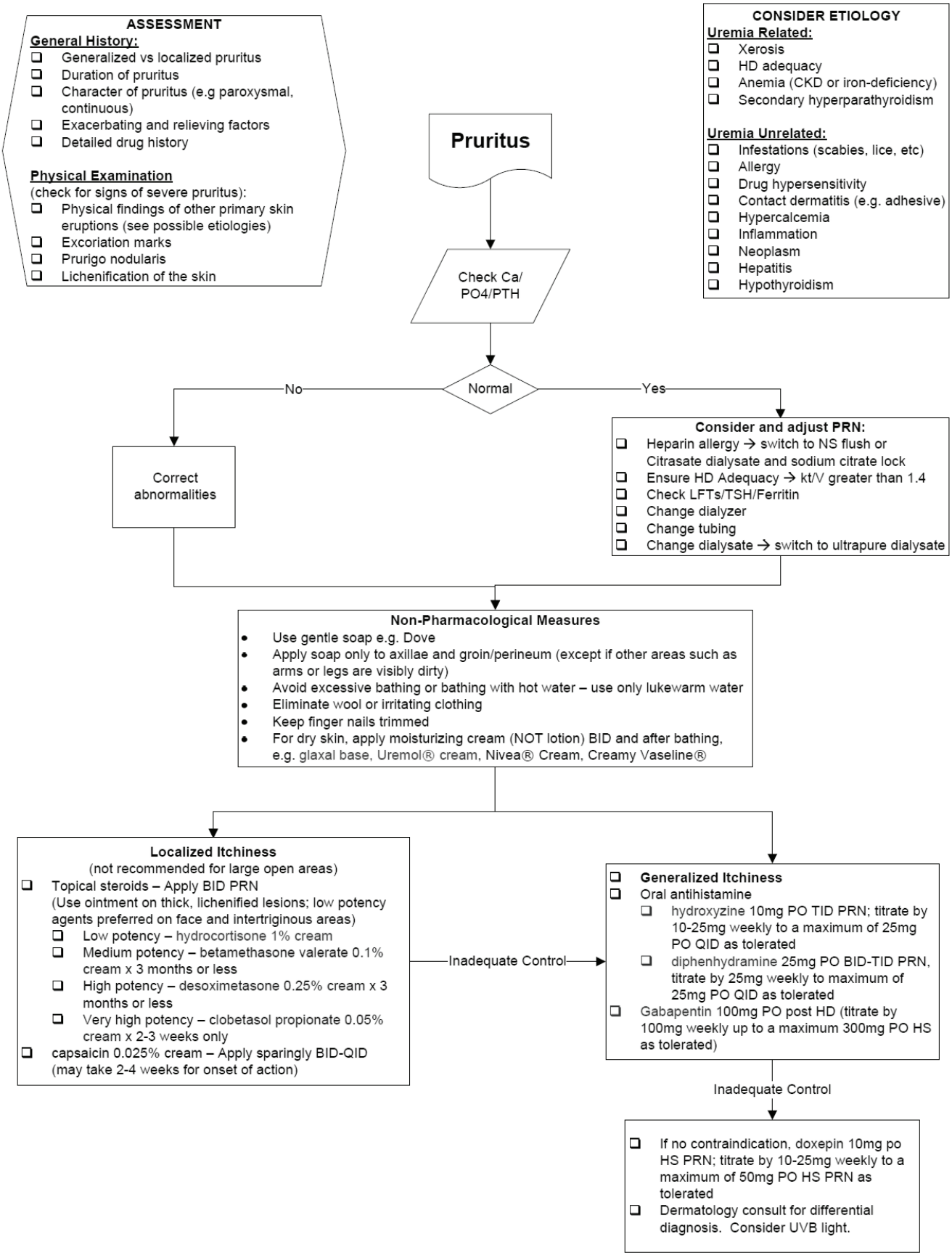
Pruritus Treatment Algorithm for Hemodialysis Patients

Draft September 21, 2012



Submitted by Marianna Leung, PharmD, BCPS, BCPP, CDE, FCSHP, Clinical Pharmacy Specialist, St. Paul's Hospital, Providence Health Care, Vancouver, BC. ***Acknowledgments: BCPRA (British Columbia Provincial Renal Agency).***

Restless Leg Syndrome (RLS) Treatment Algorithm for Hemodialysis Patients: Supplemental Evidence for Treatment Options

Submitted by Marianna Leung, PharmD, BCPS, BCPP, CDE, FCSHP, Clinical Pharmacy Specialist, St. Paul's Hospital, Providence Health Care, Vancouver, BC *Acknowledgments: BCPRA (British Columbia Provincial Renal Agency).*

RLS should only be treated if patients have severe and bothersome symptoms, which impair their sleep or quality of life. In terms of non-pharmacological strategies, correct iron deficiency, if applicable, as iron is a cofactor in dopamine production. Consider a trial of abstinence from alcohol, caffeine and nicotine. Rule out any offending medication(s) that may be contributing and reducing the dose or discontinuing, if feasible. Refer to the list of offending medications in algorithm. Consider a trial of mental alerting activities, such as video games or crossword puzzles, to reduce symptoms at times of boredom.

In terms of pharmacotherapies, available literature in hemodialysis patients is limited. Most studies are of small sample size, from single centre, have significant drop-outs and short follow-up. Recommendations are largely extrapolated from the general population and based on expert opinions.

Evidence:

Levodopa

In a randomized, double-blind, placebo-controlled, crossover trial[1] of 5 hemodialysis patients with uremic RLS, levodopa/carbidopa 100/25mg 1 hour before HS was compared to placebo x 1 week with 1-week washout. There was no consistent subjective improvement in sleep quality, sleep latency, the number of awakenings or RLS symptoms. The mean percentage of periodic limb movement (PLM) while asleep was 15.1 ± 4.9% with placebo and decreased to 8.6 ± 4.0% with levodopa/carbidopa (p=0.014). The mean PLM index while asleep was 101.0 ± 29.1 with placebo and was significantly decreased to 61.0 ± 28.3 with levodopa/carbidopa (p=0.006).

In another randomized, double-blind, placebo-controlled, crossover trial[2] of 11 HD patients, levodopa/benserazide 100/25mg to 200/50mg 1 hour before HS compared to placebo x 2 weeks without washout was shown to improve few nocturnal awakenings, sleep quality, general condition and quality of life and to decrease severity of RLS, respectively. No severe adverse effects reported.

Wetter et al[3] showed that levodopa was more effective than placebo in reducing PLM index and improve in sleep quality in a randomized, double-blind, placebo-controlled, crossover trial of 11 uremic patients with RLS.

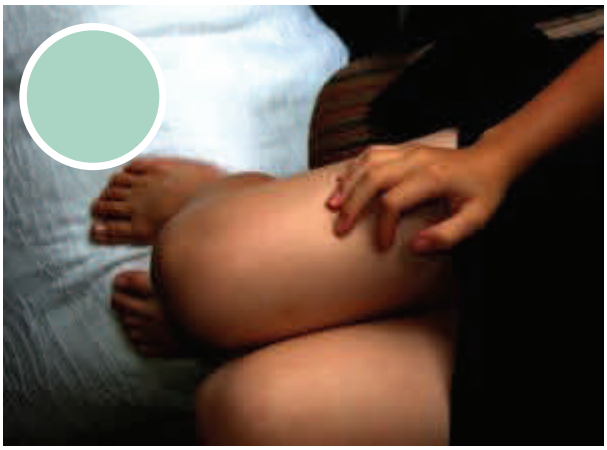
Pramipexole

In an open label[4] of 10 hemodialysis patients with RLS with 8 month follow-up, pramipexole showed an improvement in the International Restless Leg Study Group (IRLSSG) severity scale and PLM index during sleep and while awake. Pramipexole was prescribed at an initial dose of 0.125 mg, 2 hours before sleep, with an optional upward

titration according to response and tolerance to a maximum daily dose of 0.75 mg, with one dose taken at least 2 hours before dialysis. Nine patients showed a response within the first week with a mean dose of 0.25mg per day. Domperidone was prescribed to control side effects. The mean score in the severity scale fell from 25.8 ± 5.75 (in the severe range) in the pretreatment evaluation to 7.7 ± 8.36 after treatment ($p < 0.005$). Sleep latency, total hours of sleep, number of awakenings, and sleep efficiency showed no significant change.

Ropinirole

In an open label, prospective, randomized, controlled crossover trial[5] of 10 hemodialysis patients, ropinirole was shown to be superior to levodopa SR in reducing 6-item IRLS score, 16.6±2.8 to 4.4±3.8 vs 16.7±3.2 to 11.1±4,respectively (p<0.0001) and



increasing sleep time. Four patients reported a complete reversion of RLS symptoms. Ropinirole dose was 0.25mg PO daily, doubling Q5days for the first 2 weeks until symptom relief, then up to a maximum of 2mg/day (mean dose was 1.45mg/day). Levodopa SR dose was 100/25mg PO daily, then doubling after 2 weeks until symptom relief (mean levodopa dose 190mg/day). Vomiting reported in one levodopa patient resulting in study discontinuation.

Gabapentin

In an open label controlled trial[6]of 15 hemodialysis patients, gabapentin 200 mg PO post-HD x 4 weeks was significantly more effective than levodopa 125 mg PO daily. The median RLS score decreased from baseline of 17 to 10 and 3 after treatment with levodopa and gabapentin, respectively. In SF-36 assessment, gabapentin improved general health, body pain and social function (P<0.001) while levodopa significantly improved body pain only (p<0.002). Gabapentin was significantly superior to levodopa for sleep quality, sleep latency (p<0.001) and sleep disturbance (p<0.000).

In a randomized double-blind, controlled, crossover trial[7] of 13 patients, gabapentin 300mg PO 3 times weekly at the end of HD x 6 week was more effective than placebo. IRLSSG rating score decreased from a mean of 5.8 ± 2.3 with placebo to 3.0 ± 2.2 with gabapentin (p<0.01). Eleven of 13 patients responded to gabapentin but not to placebo, one responded to placebo but not gabapentin while one responded to neither drug. Lethargy was reported.

Clonidine

In a randomized, double-blind, placebo-controlled, parallel study[8], clonidine 0.075mg PO BID was compared to placebo x 3 days in 20 patients. Complete relief of symptoms was noted in 8/10 pts, marked alleviation in 1/10 patients and unchanged symptoms in 1/10 patients treated with clonidine, compared with placebo (p<0.001).

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Restless Leg Syndrome (RLS) Treatment Algorithm for Hemodialysis Patients

Draft September 21, 2012

Assessment

- Rule out mimic disorders
- Rule out drug-induced RLS
- Assess risk/contributing factors
  - Iron deficiency
  - Sleep deprivation
  - Positive family history
  - Rheumatoid arthritis or Sjogren's
  - Pregnancy

Mimic Conditions

- Movement disorders: akathisia, ADHD
- Restlessness secondary to anxiety, depression, psychotic disorders
- Local leg pathology: e.g. peripheral neuropathy, myelopathy, peripheral venous congestion
- Positional discomfort

Drug-induced RLS

- Dopamine antagonists:
  - Antipsychotics: pimozide, haloperidol, olanzapine, risperidone
  - Metoclopramide, promethazine
- Antidepressants:
  - Mirtazapine (up to 28%)
  - SSRI (<5%) e.g. citalopram, escitalopram, fluoxetine, paroxetine, , sertraline
  - SNRI's (<5%), e.g. duloxetine, venlafaxine
- Stimulants: alcohol, caffeine, nicotine
- Others: TCA's, carbamazepine, lithium

Initial Recommendation

- Discontinue or reduce offending drug, if feasible
- Correct Iron deficiency – may prevent initial augmentation with dopaminergic therapy
- Encourage good sleep hygiene (see insomnia flowchart)

http://phc.eduhealth.ca/PHC_PDFs/FM/FM.900.St82.PHC.pdf

Medication options

AVOID opioids and quinine

* If RLS symptoms occur during HD, give medication prior to HD

- ❑ ***For intermittent RLS***, levodopa/carbidopa (Sinemet®) 100/25 mg tablet – ½ tablet PO HS*, titrate Q3-7days to effect up to 200/50 mg PO HS*. If patient awakens in the middle of the night with RLS, use CR formulation. (levodopa doses ≥200 mg may increase risk of augmentation)
- ❑ ***For daily RLS***, dopamine agonists
  - Compared to levodopa, decreased risk of augmentation but increased incidence of hypotension and nausea. Caution re sleep attack (driving is not recommended).
  - ❑ **ropinirole** 0.25 mg PO 2 hours prior to HS*; increase by 0.25 mg PO Q7days to effect up to a maximum of 4 mg/day (PREFERRED)
  - ❑ **pramipexole** 0.125 mg PO 2 hours prior to HS*; may increase by 0.125 mg PO Q7days to effect up to a maximum of 0.75 mg/day
- ❑ ***If ineffective with dopaminergic agent or RLS with painful neuropathy,***
  - ❑ gabapentin 100 mg po HS*; titrate by 100 mg Q7days to a maximum of 300 mg PO HS*
  - ❑ **pregabalin** 25 mg po HS*; titrate by 25 mg Q7days to a maximum of 75 mg PO HS*

Refractory symptoms

- ❑ Benzodiazepines
  - ❑ Preferably avoid secondary to potential for sleep dependency, questionable efficacy and adverse effects due to clonazepam's long half-life. If severe insomnia, refer to Insomnia Treatment Algorithm
  - ❑ clonazepam 0.5 mg PO HS*, titrate by 0.5 mg Q7days to a maximum of 2 mg po HS
- ❑ clonidine 0.05 mg po HS if patient is not hypotensive

Submitted by Marianna Leung, PharmD, BCPS, BCPP, CDE, FCSHP, Clinical Pharmacy Specialist, St. Paul's Hospital, Providence Health Care, Vancouver, BC . ***Acknowledgments: BCPRA (British Columbia Provincial Renal Agency).***

Nutrition and Chronic Kidney Disease
Renal Pharmacists Network Presentation Nov. 15, 2012

Submitted by Naomi Taylor, Registered Dietitian, Vancouver General Hospital Renal Program, Vancouver, BC

For patients with chronic kidney disease (CKD), there is no standard "renal diet". Each patient is assessed individually and diet recommendations are made based on level of residual renal function, lab data, current nutritional status, treatment modality, co-morbid conditions and social/economic factors. Guidelines based on treatment modality are outlined in Table 1 (1,2).

Nutrition Guidelines for Kidney Disease*

* K/DOQI 2000, EBPG 2007

	CKD (chronic, not on dialysis)	Hemodialysis (conventional)	Peritoneal Dialysis	Hemodialysis (Nocturnal)
Pro (g/kg)	0.8 - up to 1.0	1.2	1.2-1.3	1.3-1.5
Na (mg)	2300	2300	2300	2300
K (mg)	Per labs	2300-3000	Per labs	Per labs
PO4(mg)	< 1100	< 1200	< 1200	Per labs
Fluid	No Restriction	1L + u/o	Usually no restriction	No restriction

Table 1. Nutrition Guilines for Kidney Desease.

PROTEIN IN CKD

In CKD Stages 1-4 protein intake is controlled to reduce uremia. Protein is the major source of nitrogen in the diet and produces nitrogenous end products that accumulate with kidney failure. Protein control also improves acidosis and may delay the progression of renal failure by reducing hyper-filtration associated with high protein intakes.

Once dialysis is initiated, protein needs increase. Amino acids are lost during hemodialysis treatments, while amino acids and intact proteins are lost with peritoneal dialysis exchanges.

Fish, poultry, meat and eggs are encouraged as they provide the highest amount of protein per volume of food with moderate amounts of potassium and phosphorus. Phosphate binders may need to be increased when dialysis is initiated due to the concomitant increased phosphorus intake.

Dairy products are high in protein but are also high in phosphorus and potassium and are therefore restricted in CKD Stages 3-5.Vegetarian proteins such as dried legumes, lentil, nuts and seeds are high in phosphorus and potassium but may be less harmful to kidneys in CKD Stage 2-4. Vegetarian diets may need more phosphate binders and the use of cation exchange resins such as Kayexelate® or Calcium Resonium® to control potassium levels.

MALNUTRITION IN CKD

Protein energy wasting (PEW) in CKD is common and is a strong predictor of morbidity and mortality (3). Up to 76% of hemodialysis and up to 50% of peritoneal dialysis patients show signs of malnutrition. Albumin less than 40 g/L is the single lab most closely associated with increased probability of death in dialysis patients. However, albumin is a negative acute phase reactant affected by a number of factors including inflammation or infection that are not related to nutrition.

Causes of PEW in CKD are multi-factorial and include nutritional and non-nutritional mechanisms (Table 2). PEW in CKD differs from simple malnutrition that is corrected with improved intake. With CKD signs of wasting may continue in the presence of adequate nutrition due to the

Causes of Protein Energy Wasting

Nutritional:

Inadequate food intake

- ◊ Anorexia due to uremia
- ◊ Altered taste sensation
- ◊ Inter-current illness and hospitalization
- ◊ Impaired ability to procure, prepare or ingest food

Non- Nutritional:

- ◊ **Dialysis Procedure**
  - ♦ Removal of nutrients by dialysis
  - ♦ Promotion of catabolic state due to inflammatory stimuli (dialysis membrane)
- ◊ **Chronic inflammation** with hypercatabolism and anorexia
- ◊ **Anemia**
- ◊ **Acidosis**
- ◊ **Endocrine Disorders of uremia**
- ◊ **Volume overload**
- ◊ **Comorbid conditions:** DM, cardiovasular disease, infection, aging

Table 2. Causes of Protein Energy Wasting

many un-modifiable factors.

Every effort is made to ensure patients are meeting nutritional requirements. However, appetites are often poor. Table 3 illustrates a variety of strategies used to help increase intake. In our institution, we give a 3-6 month trial of intradialytic parenteral nutrition (IDPN) in those patients who cannot meet their nutritional needs with nutritional supplements. Other alternatives include a 1-3 month trial of zinc supplementation (elemental zinc 10 mg daily) for altered taste and megestrol (Megace®) 160 mg daily given in single or two divided doses to stimulate appetite

Improving the Nutritional Status of CKD Patients

- Liberalize the diet
  - Accommodate food preferences
  - Involve family and friends
- Supplements
  - Ensure Plus, Nepro, Glucerna
  - Protein Powder
  - IDPN (intra-dialytic parenteral nutrition)
  - Multivitamins and minerals
  - Zinc for dysguesia
  - Appetite stimulants
- Meal delivery programs
- Home making services

Table 3. Improving the Nutritional Status of CKD Patients.

NURTITIONAL SUPPLEMENTS

Nutritional supplements are used frequently. Nepro Carb Steady or Novosource Renal are usually the supplements of choice; they are more concentrated with 2 kcals/ml and are lower in phosphorus and potassium. Ensure Plus or Boost Plus and Glucerna or Resource Diabetic (for diabetics) are not renal friendly being high in phosphorus and potassium, however, they are provided in flavor choices often preferred by patients. If overall intake is poor, their use is unlikely to exceed acceptable levels of phosphorus and potassium.

Protein aversion, particularly red meat, is common in CKD. Using Beneprotein Instant Protein Powder is a convenient way for patients to increase protein intake. It can be added to soft foods such as oatmeal or mixed into beverages with minimal change to flavor. One scoop or packet (7 grams) mixes readily into 125 ml soft food or beverage.

PHOSPHORUS

Elevated phosphate levels in CKD are associated with increased morbidity and mortality (4). Phosphate is managed through dietary phosphorus restriction (but not at the expense of meeting protein needs), phosphate binding medications and dialysis. Conventional dialysis removes some phosphorus however nocturnal dialysis (> 18 hours a week) causes significant losses often requiring the addition of phosphate to the dialysate in addition to a high phosphorus diet.

Most CKD patients are on phosphorus restricted diets. The diet is challenging as phosphorus is found in many foods. There are two main forms: organic and inorganic.

Organic phosphorus is found in animal and plant foods and is 40 – 60 % absorbed. Highest amounts are found in dairy products, dried beans, peas and lentils, nuts and seeds, whole grains and chocolate. These foods are limited to 1-2 small servings a day e.g.1/2 cup milk or yogurt, 1 inch cube cheese, 2 tablespoons peanut butter.

Inorganic phosphorus is added to foods during processing. These hidden phosphorus additives are used as stabilizers, leavening agents, color and flavor enhancers, and tenderizers. They are almost 100% absorbed and it is estimated that 10-30% of dietary phosphorus comes from these additives. It is everywhere (5).

Common foods with phosphorus additives include deli meats, battered fish, frozen seasoned chicken breasts, Butterball TurkeyÒ, pancake and waffle mix, frozen waffles, frozen bread dough, puddings, processed cheese, colas, some beverages.

It is difficult to keep up lists of products with phosphorus additives. Manufacturers frequently change ingredients. Patients are taught to read labels and avoid any product with ingredients containing the letters “PHOSPH” E.g. Sodium acid pyrophosphate. Phosphorus is currently not required by law to be listed in the “Nutrition Facts Table” . Thus, patients must look under the “ingredients” list to find these hidden phosphate additives .

The increasing use of phosphate additives may have implications for the healthy population. Serum phosphorus levels have been shown to have a continuous association with increasing risk for morbidity and mortality within the normal reference range (6).

PHOSPHATE BINDERS

The use of phosphate binders is critical for phosphate control in CKD. It is impossible to lower dietary phosphorus

adequately as the diet would be unpalatable. Patients often have difficulty taking phosphate binders correctly. They don't always understand where the phosphorus is or why or how to take their binders.

Phosphate binders should be taken with meals and phosphorus containing snacks, ideally just before the first bite of food. Often binders are prescribed TID but with day-to-day and meal-to-meal variations, some patients are taught to "titrate" binder use to phosphate intake. Total prescribed dose should never be exceeded.

GI complaints are frequent. Constipation is commonly associated with calcium containing binders. Laxatives containing magnesium or phosphate should be avoided as well as fruit laxative ("Fruitlax") or prune juice due to their high potassium contents.

SODIUM

Sodium restriction is indicated for blood pressure and fluid management. The recommended sodium Adequate Intake for the healthy population is 1500 mg a day (7). The Tolerable Upper Limit, the highest limit without increased risk, is 2300 mg a day. Canadian intake of sodium is much higher with a mean of 3400 mg a day. High risk groups such as persons with CKD, hypertension, diabetes, persons >50 years old, African American and South Asians are recommended to limit to the lower level. However, diets less than 2000 mg are difficult to achieve and tend to be unpalatable.

To achieve sodium control it is not enough to advise patients to remove the saltshaker. Only 11% of sodium intake comes from salt added to cooking or at the table. The majority, 77%, comes from processed foods, restaurant eating or take out foods.

Using unprocessed, whole foods prepared from scratch reduces sodium intake. To add flavor, unsalted fresh or dried herbs and spices or premade seasoning blends can be used as well as fresh lemon and lime juice or vinegars to bring out the natural sodium flavor. Many low sodium products such as unsalted soup broths and low sodium snack foods are now available.

FLUID

Fluid restriction is required for most conventional hemodialysis patients. The guideline is one liter of fluid plus an amount equivalent to the 24 hour urine output. This results in fluid retention between hemodialysis treatments of approximately 3-4% of body weight.

Many patients have no urine output therefore their fluid intake is limited to one liter a day. This includes anything liquid at room temperature such as water, ice, tea, coffee, milk, juice, soup, gelatin and nutritional supplements such as Nepro.Limiting fluid to such a low level is challenging and it is essential to control thirst by limiting sodium intake and for patients with diabetes, controlling blood glucose. Medications may also contribute to thirst from anticholinergic side effects of tricyclic antidepressants e.g. nortriptyline, or centrally-acting antihypertensives such as clonidine.

POTASSIUM

Potassium management in CKD involves diet, dialysis and medications. Hemodialysis patients often run chronically higher than normal potassium levels without adverse affects (up to 5.6 mmol/L). Sudden shifts of potassium either up or down are more dangerous and should be avoided.

Peritoneal dialysis and nocturnal dialysis patients may need high potassium diets and possibly potassium supplementation due to the efficient daily removal of potassium. Most conventional hemodialysis patients and many CKD Stages 2-4 patients need dietary potassium restriction. Some also need cation exchange resins such as Kayexelate® or Calcium Resonium® to achieve safe potassium levels.

Common high potassium foods are listed in Table 4. A restricted potassium diet limits low and moderate potassium fruits and vegetable to 2-3 half cup servings of each per day.

Portion control is important, large amounts of even low potassium foods can result in high potassium intake. These limited amounts of fruits and vegetables do not meet Canada's Food Guide recommendations.

Some High Potassium Foods

Fruit	Vegetables	Other
Avocado	Potato	Co-Salt/Nu Salt
Banana	Sweet potato	Dairy
Orange	Tomato	Nuts and seeds
Dried Fruit	Tomato products	Legumes, dried beans
Papaya	Squash	Mince meat
Nectarine	Spinach	Ovaltine
Cantelope	Beets	Potato Chips
Kiwi	Taro	Chocolate
Honeydew melon	Kale	Granola
Prune Juice	Brussel Sprouts	

Table 4. Some High Potassium Foods.

Salt substitutes containing potassium chloride e.g. Co-salt or Nusalt are dangerous for CKD patients and should not be used. Renal diabetic patients should not treat low blood sugar with orange juice as it is high in potassium; instead, they should be taught to increase low blood sugar with apple juice, regular pop or low fluid sugars such as glucose tablets or hard candy.

Hyperkalemia may result from many non-dietary causes including the use of medications such as ACEs, ARBs, and potassium sparing diuretics e.g. spironolactone.

Starfruit (Carambola) must never be eaten in CKD. Although moderate in potassium it contains a neuro-toxin that has caused hiccups, nausea, vomiting, insomnia, mental confusion, convulsions and death in this population.

VITAMIN AND MINERAL SUPPLEMENTS

The water soluble vitamins, B, C and folate are supplemented in CKD Stages 4-5 due to dietary restrictions and losses into the dialysate (8). Fat soluble vitamins are not recommended. Vitamin A may accumulate due to reduced renal clearance and high levels have been associated with osteoporosis, and there are no indications of deficiencies of Vitamins E or K. Vitamin D is assessed as part of the bone mineral management in CKD. In cases of severe malnutrition multivitamin and mineral supplements may be prescribed.

ADHERENCE

Many patients have difficulty with their renal diet. The diet is for life and it is hard to maintain. Patients live in a culture of eating out and convenience and fast foods. Patients often receive advice from different sources and the messages are often contradictory. For example, diabetes and healthy heart guidelines stress whole grains while these are limited on the renal diet.

The diet, medications and dialysis regimes are all complex. Patients have substantial amounts of information to learn and practices to integrate into their lives. Continual monitoring and support from the renal team is fundamental to helping patients manage their chronic illness.

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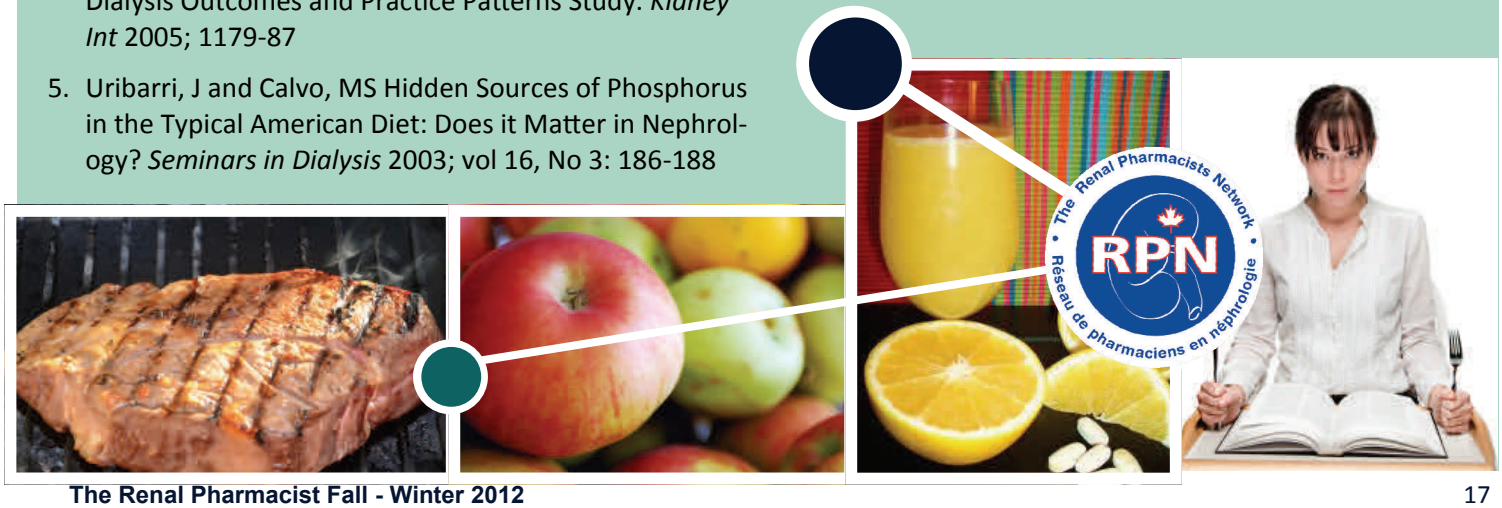




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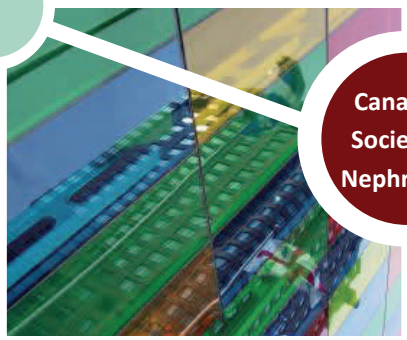


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KDIGO Clinical Practice Guideline for the Evaluation and Management of Chronic Kidney Disease.

Kidney Disease: Improving Global Outcomes (KDIGO) CKD Work Group. Kidney Int Suppl. 2013;3:1-150.

Just published Jan 2013! These recent guidelines outline the new CKD staging system that incorporates prognosis by GFR and albuminuria categories. It covers a variety of topics for CKD non-dialysis patients including "Medication management and patient safety in CKD" (Section 4.4).

KDIGO Clinical Practice Guideline for the Management of Blood Pressure in Chronic Kidney Disease.

Kidney Disease: Improving Global Outcomes (KDIGO) Blood Pressure Work Group. Kidney Int Suppl. 2012;2:337-414.

Published Nov 15, 2012. These guidelines recommend blood pressure targets for CKD non-dialysis based on urinary albumin excretion rates.

KDIGO Clinical Practice Guideline for Acute Kidney Injury.

Kidney Disease : Improving Global Outcomes (KDIGO) Acute Kidney Injury Work Group. Kidney Int Suppl. 2012;2:1-138.
Link title to:

These recent guidelines include a section on "Prevention of aminoglycoside- and amphotericin-related AKI" (Section 3.8).

KDIGO Clinical Practice Guideline for Lipids.

(To be published February 2013)

Medication Dosing in Critically Ill Patients With Acute Kidney Injury Treated With Renal Replacement Therapy.

Scoville BA, Mueller BA. Am J Kidney Dis. 2012 Nov 2. pii: S0272-6386(12)01254-1. doi: 10.1053/j.ajkd.2012.08.042. [Epub ahead of print]

Using a case, the authors recommend dosing of 5 different antibiotics (daptomycin, gentamicin, meropenem, piperacillin/tazobactam, vancomycin) in intermittent hemodialysis, prolonged intermittent renal replacement therapy and continuous renal replacement therapy.

Antidepressants for depression in stage 3-5 chronic kidney disease: a systematic review of pharmacokinetics, efficacy and safety with recommendations by European Renal Best Practice (ERBP).

Nagler EV, Webster AC, Vanholder R, et al. Nephrol Dial Transplant. 2012 Oct;27(10):3736-45.

This is a systematic review on the pharmacokinetics, efficacy and safety of antidepressant drugs when used in patients with CKD stages 3 to 5. The authors identify antidepressants requiring dosage adjustments.

Asking the question again: are cation exchange resins effective for the treatment of hyperkalemia?

Kamel KS, Schreiber M. Nephrol Dial Transplant 2012;27:4294-7.

Impact of pharmacist-managed erythropoiesis-stimulating agents clinics for patients with non-dialysis-dependent CKD.

Aspinall SL, Cunningham FE, Zhao X et al. Am J Kidney Dis 2012;60:371-9.

A recent publication involving 10 Veterans Affairs Medical Centers with pharmacist-managed ESA clinics. Pharmacist-managed ESA clinics provided more hemoglobin values within targets and lower ESA doses relative to usual care.

Comparison of alteplase (tissue plasminogen activator) high-dose vs. low-dose protocol in restoring hemodialysis catheter function: The ALTE-DOSE study.

Yaseen O, El-Masri MM, El Nekidy WS, Soong D, et al. Hemodial Int. 2012 Nov 26. doi: 10.1111/hdi.12004. [Epub ahead of print]

This retrospective analysis conducted at Hotel-Dieu Grace Hospital in Windsor, Ontario, compares use of 1 mg versus 2 mg of intraluminal alteplase for hemodialysis catheter dysfunction due to thrombosis. The authors found that the 2 mg dose was optimal. Congratulations to Derrick Soong who was involved in the study and is a member of RPN!

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Gold ($5,000 - $9,999)

SANOFI

Otsuka

LEO Pharma Inc.

Silver ($2,500 - $4,999)

janssen PHARMACEUTICAL COMPANIES OF Johnson & Johnson

Roche

AstraZeneca CANADA

Shire

Bronze (< $2,500)

SERVIER