

The Renal Pharmacist



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Issue 1

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A biannual Insight into the Renal Pharmacist Network



View from the Chair

Wow, where has the time gone. 2015 went by in a flurry and I can't believe we are already into 2016. The RPN had another exciting year of education events. The education day at the CSN in Montreal last year was well attended and very well received. The highlight may have been the round table discussions at the end of the day where everyone got to brainstorm and bounce our renal ideas off one another. It was a great opportunity to connect with our colleagues across the country and learn about everyone's regional practises. We were also fortunate enough to have a wine and cheese, where we continued to connect with our colleagues and sponsors. It was a great day overall. Education days were also held across the country. Vancouver's was a great success, Calgary's was well attended, and Winnipeg's was well received. We were lucky enough to have Cali, our new Chair for 2016 there to

2015 went by in a flurry...

have the education day back in Winnipeg. I am looking forward to the rest of 2016 and the new opportunities it brings. Looking ahead, we are planning a smaller get together for the RPN at CSN in Halifax, where we will be able to review a couple relevant topics, while planning for our biggest education event in Toronto for the fall. Looking forward to a great year under Cali's direction.

Carlee Balint
RPN Chair 2016



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Biography: Clifford Lo

Clifford Lo, is the new chair elect for the Renal Pharmacist Network. He is currently the Provincial Pharmacy Lead for Special Projects & Initiatives at the British Columbia Provincial Renal Agency (BCPRA) and a Clinical Pharmacy Specialist in the Fraser Health Renal Program. He obtained his PharmD from the University of Washington in 2010 and is a Board Certified Pharmacotherapy Specialist. Dr. Lo is also trained in epidemiology and health economics through his Masters in Health Administration and has completed a 2-year administrative fellowship at the BCPRA. In addition to his clinical and administrative roles, he has research interests in the areas of health policy and access and has published half a dozen peer-reviewed papers in this area. He is particularly interested in the decision-making process for approval, reimbursement, and utilization of medications for renal diseases. Lastly,

Dr. Lo is committed to the development and training of pharmacy students who are practice ready and able to manage complex renal patients upon graduation; together with his renal pharmacist colleagues in BC, they have created and offer an extremely popular renal pharmacotherapeutics elective at the University of British Columbia.

Welcome Cliff!

Upcoming conferences:

The RPN is proud to host a Renal Pharmacists Round Table Discussion at the **Canadian Society of Nephrology Annual General Meeting 2016** in Halifax, Nova Scotia

Date: May 12, 2016

Time: 4:00pm to 5:30pm

Location: daMaurizio Restaurant, 1496 Lower Water St., Halifax

Online registration is now open until April 28, 2016

Space is limited so please register as soon as possible. Note that registration is strictly restricted to renal pharmacists. Please visit the following webpage for more information and online registration:

<http://renalpharmacists.net/civicrm/event/info?reset=1&id=47>

Highlights: RPN Vancouver Continuing Education Evening

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

On November 10th, the RPN hosted the Vancouver Continuing Education Evening at the Croatian Cultural Centre. This year, we had the pleasure to have Sharon Leung and Karen Shalansky presented a new website based database created by some BC renal pharmacists reviewing the safety of herbal products in chronic kidney disease, dialysis as well as renal transplant patients. The website (www.herbalckd.com) currently contains safety monograph for about 25 herbals products and is updated monthly with new herbal product monographs. During the presentation, Sharon discussed the definition of herbal product as per Health Canada. She reviewed the demographic characteristics of herbal users in BC, as per PROMIS database. In our retrospective study, 22% and 20% of CKD non-dialysis and dialysis patients respectively have herbal products on their medication profile, and this number decreases to 18% for renal transplant patients. The top 5 herbal products reported in PROMIS database were: vitamin B12, omega-3, vitamin C, glucosamine and coenzyme Q10. Karen discussed how literature search is performed to build the website monograph and how the safety rating recommendation is based on the category established by Natural Medicines database. She also guided us through the website to make

sure that users can use it to its full capacity. To have a more interactive evening, we then presented 5 cases from our practice in which drug related problems (DRPs) in link to herbal consumption were identified. The participants were asked to resolve the DRPs with the help from the website and to discuss their reasoning with the group. Participants were also invited to share their comments on the website. Our education evening was well received by the participants and it was a great occasion to share ideas and opportunities with our colleagues.



Highlights: RPN Calgary Second Annual Continuing Education Evening

Submitted by Carlee Balint, BSP, ACPR, Foothills Medical Center, Alberta

This year's RPN education event was another success in Calgary, where we were able to get 14 pharmacists out to attend an evening where Dr. Louis Girard reviewed Hypertension and CKD. There was a variety of pharmacists from different specialties, including nine pharmacists that work directly in Nephrology patient care areas. This included two pharmacists who drove from Red Deer for the evening as well as a pharmacist that works in paediatric nephrology. The other pharmacists who attended were from a variety of internal medicine and cardiology specialties. Dr. Girard had a great presentation that covered The Management of Hypertension: A Focus on Renal Disease and Resistant Hypertension.

His talk took us through guideline recommendations for those with Chronic Kidney disease as well as diabetics while reviewing the ACCORD study highlighting that those on ACE

-I plus Amlodipine has less occurrence of primary end point (8.8% vs 11% on death from CV disease, MI, Stroke, Revascularization). He discussed resistant hypertension and its common causes, including non-compliance, lifestyle, OTC medications as well as its medical causes, including obstructive sleep apnea, endocrinopathies, renal parenchyma disease and renal artery stenosis. Noting the prevalence of CKD in those with diagnosed hypertension is 32% and those with albuminuria with ACR's of >300 mg/g have a multivariable adjusted prevalence ratio of 2.44 of resistant hypertension versus the reference population of those with an ACR of < 10 mg/g.

Dr. Girard then discussed proteinuria, who and how we should measure it. He reviewed the different screening types for measuring including MACR, UTPCR and the comparisons of the units for each. Proteinuria was shown

to be of importance first by Hemmelgarn et al in JAMA 2010. This then prompted the changes to be made to the KDIGO heat map that we now use today to stage CKD. He reviewed the outcomes in mortality, ESRD, and regression of ESRD and how they all trend towards improvement with ACE/ARB.

Finally we discussed the SPRINT trial and its significance in treating hypertension. When treating BP and reaching a systolic blood pressure (SBP) of 120 mmHg, only 61 patients need to be treated in order to prevent a primary event in one patient as compared to treating to a SBP of 140 mmHg.

But that the serious adverse events were more frequent in the low BP group and the number needed to harm was ~60 as well.

In the end Dr. Girard also provided us with some practical tips he uses in treating hypertension, including his “magic bullet” or adding doxazosin or terazosin in those with very resistant hypertension.

Overall it was a great review of new and old literature with a bit of practical experience. There were a number of great discussion topics and questions from the group.

Highlights: RPN Winnipeg Continuing Education Evening

The recent RPN continuing education evening held in Winnipeg involved two speakers: Dr. Andrea Mazurat, Nephrology Fellow, presented an overview of the B-blocker dialyzability study and the SPRINT trial; and Lori Wazny, an extended practice pharmacist and pharmaceutical care coordinator in the

Manitoba Renal Program presented about the concerns with the data used to classify the dialyzability of bisoprolol and metoprolol. The event was very well attended by renal pharmacists and a good learning opportunity for all. A brief summary of the talk given by Lori Wazny as well as a summary of the SPRINT trial is provided below.



Issues in Categorizing the Dialyzability of Bisoprolol and Metoprolol

Submitted by Lori Wazny, B.Sc.(Pharm), Pharm.D., EPPh, Extended Practice Pharmacist, Manitoba Renal Program

On Feb 18th, the RPN held an educational session in Winnipeg where Dr. Andrea Mazurat, Nephrology Fellow, presented an overview of the B-blocker dialyzability study.(1) This study has already been nicely summarized in the Summer 2015 edition of the RPN newsletter by Derrick Soong (<http://www.renalpharmacists.net/sites/renalpharmacists.net/files/newsletters/summer2015.pdf>). I then presented the concerns with the data used to classify the dialyzability of bisoprolol as low dialyzable and metoprolol as high dialyzable. This will be the focus of this article.

The following order of references for classification of dialyzability was used by the authors:

1. Product monographs.

According to the authors, the product monographs provided “clear statements [on dialyzability] for all drugs except metoprolol”. Concerns: What type of dialyzer was used? (low flux vs high flux) Bisoprolol

monographs just state “limited data suggest that bisoprolol is not dialyzable” with no references or further explanation.

2. Dialysis of Drugs Handbook 2013 edition.

The 2013 Dialysis of Drugs handbook actually states that bisoprolol is not removed by low flux dialyzers and that there is “no data” for high flux dialyzers. What was published in the Dialysis of Drugs column was that bisoprolol is “not significantly dialyzable” (Table 4).(1)

In contrast, the Micromedex database under the Pharmacokinetics section states that bisoprolol is removed and references the same pharmacokinetic study used by Weir et al to say that it is not removed. (2)

For metoprolol, the 2013 handbook stated “likely” to be removed by high flux dialyzers but the 2014 app now states “No” but “Likely” for “active metabolites”. However, the metoprolol product monograph states

that it is 95% metabolized to inactive metabolites and the remaining 5% is unchanged drug.(3)

3. Four review articles.

These were general review articles on treatment of intradialytic hypertension (n=2), antihypertensives in dialysis (n=1) and a KDIGO Controversies Report on blood pressure in CKD 5D (n=1). The authors stated that in these articles the categorization of metoprolol varied.

Concerns: Why reviews? Why not primary literature? Of note, it is only these review articles and the Dialysis of Drugs 2013 categorization which are published as Table 4 in the Weir study.(1)

4. Lastly, the authors examined the primary literature on pharmacokinetics (PK) of B-blockers in patients receiving hemodialysis.

Concerns: This primary literature summary was only published as a supplemental table (Table S1) and is not included in the main article. Other comments listed below.

Table S1 lists the PK properties of each B-blocker which determine dialyzability:

1. Molecular Weight:

Table S1 incorrectly states the molecular weight of all B-blockers. Instead what is listed in that column is the molar mass (g/mol).

The molecular weight (Daltons) is higher than the molar mass listed for bisoprolol (325 listed vs 767 Da actual) and metoprolol tartrate (267 listed vs 685 Da actual). However, these are still small molecules that could be removed by high flux dialyzers. Only metoprolol tartrate is available in Canada according to the Health Canada Drug Product Database.(4)

2. Protein binding:

Protein binding is low for bisoprolol (30-36%) and metoprolol (10% tartrate salt) so removal might also be expected.

3. Volume of distribution (Vd)

A Vd greater than 3L/kg means the drug exceeds plasma volume and distribution into extravascular spaces is expected (5) and so it may be less likely to be dialyzable.

Vd is 3 L/kg for bisoprolol.

Vd is listed as 3.2 L/kg for metoprolol. However, this

is just the lower end of the Vd range for the tartrate salt (which Micromedex lists as 3.2-5.6 L/kg). Metoprolol does cross the blood brain barrier (i.e. similar to propranolol) and CSF levels are close to plasma levels. The Vd listed in Table S1 for propranolol (Vd 4.9 L/kg; low dialyzable) is similar to metoprolol which was classified as high dialyzable.

4. Renal excretion

Bisoprolol is 50-60% renally excreted as unchanged drug and 50% renally excreted as inactive metabolites and so its half-life is prolonged in stage 5 CKD as noted in the supplemental table. This high level of renal excretion also makes it more likely to be removed by dialysis where renal clearance is largely replaced by dialyzer clearance.(5)

Metoprolol, on the other hand, is extensively metabolized by CYP 2D6 and only 5-10% of the tartrate salt is renally excreted as unchanged drug, making it less likely to be removed by dialysis.

In examining these four determinants of drug removal by hemodialysis, it appears that bisoprolol is likely to be removed (small molecular weight; low protein binding; Vd 3L/kg; highly renally excreted) and metoprolol is less likely to be removed (Vd>3L/kg; low renal excretion).

Only one study examining hemodialysis clearance of bisoprolol has been published.(2) This small (n=11) 1999 study states that bisoprolol was "dialyzable" with a plasma reduction of 25.4% (5 mg dose, n=6) and 34.8% (2.5 mg dose, n=5) and used a polysulfone dialyzer (only described as "PS; Fresenius") but was most likely a high flux dialyzer. This is a similar plasma reduction to atenolol (34%) which was characterized as high dialyzable and is listed in the same supplementary table (Table S1). Typically, if dialysis clearance increases plasma clearance by 30% or more, dialysis clearance is considered to be clinically important.(5)

It appears the B-blocker authors chose to ignore this study's results. In another supplementary table (Table S2 Limitations of the available PK studies of B-blockers in hemodialysis), they state that in this study the clearance was estimated "by the A-V difference method only". and "variances about the mean clearance rates [were] not reported". However, this is the best, although limited, data we have to date on removal by a high flux dialyzer. The accompanying editorial also questions the authors categorization of bisoprolol as low-dialyzable stating that "although bisoprolol is categorized as hydrophilic, just as atenolol is, it was classified in the low-dializability category in the study".(6)

Metoprolol has no studies examining clearance during hemodialysis. The two PK studies provided in Table S1 only examined metoprolol half-life on non-dialysis days.(7,8) Metoprolol was administered 20-24 hours prior to hemodialysis so would have been metabolized to inactive metabolites prior to the start of dialysis. In addition, these two studies were published in 1978 and 1980 and they did not specify the dialyzer used but it was likely a low flux dialyzer.

A Medscape article also questions the authors' dialyzability categories (9):

"Although they categorized beta blockers simply into high- and low-dialyzability categories, the authors acknowledge that the pharmacokinetics of beta blockers are complicated: "[W]e recognize that the dialyzability of a drug is a complex interaction among many aspects of its pharmacokinetics and the dialysis prescription. Although a drug's volume of distribution, molecular weight and protein binding are readily available, the literature lacks data on factors such as the degree [of] red blood cell binding and changes in hepatic metabolism," the authors write.

The investigators also point out that bisoprolol has a high degree of beta-1 selectivity, which might play a role in its superior safety profile in the dialysis population."

Take Away:

This is really a study of bisoprolol versus metoprolol tartrate and not a study of low dialyzable versus high dialyzable B-blockers. Ninety six percent of patients in the study received bisoprolol and 70% received metoprolol tartrate. This point is also made mention of in the accompanying editorial.(6)

Based on current limited data, it appears that bisoprolol is removed by hemodialysis and that metoprolol may not be removed (however, no published dialysis clearance studies for metoprolol). This is in opposition to the authors' categorization of these two B-blockers.

As mentioned by the authors in their limitations section, they were not able to look at timing of dosing (i.e. subjects who received a dose post dialysis) or the type of dialyzer used.

Another issue with metoprolol, not discussed by the study authors but one that pharmacists should be aware of, is its extensive metabolism by CYP 2D6. Ultrarapid metabolizers of 2D6 include 4% of white North Americans but 10% of Greeks and Portuguese and 20% of Saudis and 30% of

Ethiopians.(10) Ultrarapid metabolizers will have a decreased effect of metoprolol. Poor metabolizers of 2D6 include 6-10% of Caucasians, 3-6% Mexican Americans, 2-5% African Americans and 1% of Asians. (10) Poor metabolizers will have decrease B1 selectivity and the potential for increased adverse effects of metoprolol due to increased blood levels of active drug. Similarly, drug inhibitors of 2D6 will produce these same effects (e.g. cinacalcet, amiodarone, bupropion, diphenhydramine, imatinib (Gleevec), paroxetine, fluoxetine, terbinafine among others). CYP 2D6, unlike most other CYP 450 enzymes, is not very susceptible to drug enzyme induction. (10)

References:

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SPRINT Trial Review

Submitted by Brad Hernden, B.Sc.(Pharm), Winnipeg Regional Health Authority Pharmacy Resident

The Systolic Blood Pressure Intervention Trial (SPRINT) aimed to determine if treating blood pressure with a systolic target of <120mm Hg is superior to the commonly known target of <140mm Hg. This is inspired by the current literature supporting systolic hypertension to be a risk factor for stroke, ischemic heart disease, heart failure and both chronic kidney disease (CKD) and end stage renal disease (ESRD). Previously, the ACCORD BP study looked at patients with Type 2 diabetes assigned to a systolic BP <120 mm Hg versus <140 mm Hg and showed no cardiovascular or mortality benefit but did show a significant decrease in strokes.

SPRINT was designed as a randomized, controlled, open-labelled trial conducted at 102 clinical sites. Inclusion into the trial required that patients be >50 years of age, have a systolic blood pressure of 130-180mm Hg, and be at increased risk of cardiovascular events. Increased cardiovascular risk was defined as cardiovascular disease other than stroke, CKD with eGFR of 20-60mL/minute/1.73m², 10 year Framingham cardiovascular risk of greater than 15%, or age of 75 years or older. Exclusion criteria included patients with a known secondary cause of hypertension, proteinuria (>1g/day), diabetes, polycystic kidney disease, glomerulonephritis treated with immunosuppressive therapy, eGFR < 20mL/min/1.73m², those with prior stroke, CV event or unstable angina in past 3 months, symptomatic heart failure within last 6 months or LVEF <35%, or previous organ transplant.

Eligible patients (n= 9361) were randomized to either a standard treatment arm targeting less than 140mm Hg or intensive-treatment arm targeting less than 120mm Hg. Once randomized, their baseline antihypertensive regimens were adjusted based on treatment algorithms. Notably the treatment algorithms are not actually determining prescriber choices, and are only a guide. The average number of antihypertensive medications used in the intensive group was 3, compared to 1.9 in the standard group.

The primary outcome was a composite endpoint of myocardial infarction (MI), non-MI acute coronary

syndrome, stroke, decompensated heart failure, death due to cardiovascular disease. Secondary outcomes include a cardiovascular composite outcome; first occurrence of any of the components of the primary outcome and all cause mortality. The renal outcome; CKD patients with an eGFR decrease ≥50% or development of ESRD, or non-CKD patients with an eGFR decrease ≥30% to a value less than 60mL/min/1.73m². Safety outcomes include adverse effects considered serious; fatal or life-threatening, requiring intervention to prevent fatality, or requiring hospitalization. Also minor adverse events including hypotension, syncope, electrolyte abnormalities, falls, or bradycardia.

Results:

The intensive treatment arm experienced a 25% risk reduction in the primary outcome (NNT = 63/3.3 years), driven mainly by a decrease in heart failure. Separation in the primary outcome was observed 1 year into treatment. The intensive treatment arm also showed a statistically significant benefit in all-cause mortality as a secondary outcome (NNT = 83/3.3 years), and separation was observed 2 years into treatment.

An excellent summary of the SPRINT trial results is freely available from RxFiles at: <http://www.rxfiles.ca/rxfiles/uploads/documents/SPRINT-BP-Trial-Overview.pdf>.

Renal Outcomes/Adverse Events:

Among those with CKD there was no significant difference in the composite outcome of a decrease in eGFR by 50% or progression to ESRD. However, there were only a small number of renal events observed (n=29 in total) and this was a low risk population for CKD progression due to the exclusion criteria.

In those without CKD, the outcome defined as an eGFR decrease of 30% to a value of less than 60mL/min/1.73m² was higher in the intensive treatment arm (NNH = 37) with a higher incidence of acute kidney injury (AKI) in the intensive group (NNH = 63) likely related to a 20% higher usage of ACE-I and ARBs in the

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intensive group. The study does not report how many subjects recovered from their AKI which makes it more difficult to assess the impact of this adverse event.

A statistically significant increase in other adverse events including hypotension (NNH = 100), syncope (NNH = 83), or electrolyte abnormalities (NNH = 200) were observed in the intensive treatment arm. Interestingly, despite the higher incidence of hypotension and syncope, the incidence of falls and bradycardia were not different between the groups.

Study limitations:

There is a lack of generalizability due to the populations excluded (e.g. diabetics, prior stroke, <50 years of age, patients in nursing homes or assisted living, patients with difficult to control blood pressure, CKD patients with proteinuria >1g/day or eGFR<20 ml/min/1.73m²). There was also a low rate of statin use in this high-risk population which may have influenced the results. Adverse events may be higher in the real-world setting where patients are not as closely monitored. Median SBP in the intensive group was 121 mm Hg, so half the patients were above this.

Implications for Practice:

A SBP target <120 mm Hg may be appropriate in patients with a Framingham risk >15% who do not have comorbidities such as diabetes, stroke, or advanced CKD. It may also be appropriate in patients who achieve SBP in the 120s without requiring a high number of antihypertensives and who are not experiencing adverse effects of therapy. Lastly, patients prescribed ACEI/ARBs or diuretics who are targeting a SBP<120 mm Hg need to be reliable and able to hold these medications when they are unable to maintain adequate fluid intake (e.g. vomiting/diarrhea) due to the risk of AKI.

Our Annual Renal Pharmacist Network Education Day is scheduled to take place in Toronto this Fall!
Stay tuned for more details!

Date: September 30, 2016



What's New in the Nephrology Literature?

A Focus on Renal Pharmacotherapeutics...

Click on the title to go to the PubMed link



Please send any articles
of interest to

renalpharmacistsnetwork@gmail.com



Battistella M, Fleites R, Wong R, Jassal SV. Development, validation, and implementation of a medication adherence survey to seek a better understanding of the hemodialysis patient. Clin Nephrol. 2016 Jan;85(1):12-22.

In this adherence study, conducted at University Health Network in Toronto, Canada, 23% of hemodialysis patients (36/156) reported being non-adherent, with reasons for non-adherence predominantly due to gaps in medication knowledge.

Wazny LD, Nadurak S, Orsulak C, Giles-Smith L, Tangri N. The Efficacy and Safety of Megestrol Acetate in Protein-Energy Wasting due to Chronic Kidney Disease: A Systematic Review. J Ren Nutr. 2016 Jan 5. pii: S1051-2276(15)00197-1.

Three randomized controlled trials and six observational studies were included in this systematic review of megestrol acetate for treatment of protein-energy wasting in patients receiving hemodialysis and/or peritoneal dialysis. The authors conclude that significant caution should be used with megestrol acetate as evidence is limited.

Hladunewich MA, Melamad N, Bramham K. Pregnancy across the spectrum of chronic kidney disease. Kidney Int. 2016 May;89(5):995-1007.

In this review of management strategies for the care of pregnant women with chronic kidney disease, the authors encourage a collaborative multidisciplinary approach with a team including pharmacists.

Sadowski CA, Lyder C, Yuksel N. Bisphosphonates for Osteoporosis in Patients with Renal Insufficiency: Pharmacists' Practices and Beliefs. Can J Hosp Pharm. 2016 Jan-Feb;69(1):14-22.

In this cross-sectional survey of 367 hospital pharmacists, 41% indicated that they would use a bisphosphonate for patients with a creatinine clearance (CrCl) of 15 to 30 ml/min, 56% indicated they would avoid a bisphosphonate for patients with a CrCl below 15 ml/min and 48% indicated that oral bisphosphonates can be used in patients with a CrCl less than 30 ml/min with dosage adjustments. This survey identifies educational gaps among hospital pharmacists regarding bisphosphate use in CKD.

Clark EG, Rodger MA, Ramsay TO, Knoll GA. Effectiveness of a computerized decision support system for anticoagulation management in hemodialysis patients: A before-after study. Hemodial Int. 2016 Mar 17. doi: 10.1111/hdi.12411.

A pharmacist-led computerized decision support system (CDSS)-assisted anticoagulation management strategy for patients receiving chronic outpatient hemodialysis and warfarin therapy was evaluated in tertiary medical center in Ottawa. In this before-after study, with an initial period of nephrologist-led anticoagulation management, there was no significant difference in median therapeutic time-in-range but there were fewer INR tests per patient per month, compared to pharmacist-led CDSS-assisted care.

The Renal Pharmacists Network would like to thank the following sponsors for their continued support and generous contributions.



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