Manage the Symptoms, Support the Needs: Impacting Patient Outcomes

Saturday, May 19 • 9:45–11 am

Note one action you’ll take after attending this session: ________________________________

1. Onco-Nephrology: A New Cancer Nursing Subspecialty
Amanda Hughes, ANP-BC, MSc, OCN
Memorial Sloan Kettering
New York City, NY

2. The Role of Nurse Clinicians and Advanced Practice Providers in the Management of Supportive Oncology Needs and Treatment-Related Side Effects for Women With Gestational Trophoblastic Neoplasia (GTN)
Nancy Anderson, CNP
Robert H. Lurie Comprehensive Cancer Center
Chicago, IL

3. Hepatitis B Outbreak: Can We Prevent It?
Patricia Karwan, DNP, APRN-BC
Care New England
Cranston, RI

4. Self-Care Support for Patients with Gastrointestinal Cancer: iCancerHealth
Nina Grenon, DNP
Dana-Farber Cancer Institute
Boston, MA
Onco-nephrology: a New Cancer Nursing Subspecialty

Date: May 19th 2018
Presenter: Amanda Hughes ANP-BC, MSc, OCN
Nurse Practitioner Onco-Nephrology, Memorial Sloan Kettering Cancer Center
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**Onco-Nephrology**
- Review of renal function
- Review of nephrotoxicity, standard therapies
- Focus on novel therapies
- Case studies
- Future directions

**Review of kidney function**
Criteria for Kidney Injury: Discrepancies

- AKI can be diagnosed if any one of the following is present: KDIGO
- Increase in SCr by ≥0.3 mg/dl (≥26.5 μmol/l) within 48 hours; or
- Increase in SCr to ≥1.5 times baseline, which has occurred within the prior 7 days; or Urine volume < 0.5 ml/kg/h for 6 hours.

Stages of AKI

- Stage 1: 1.5–1.9 times baseline or greater than or equal to 0.3mg/dl increase in serum creatinine
- UOP <0.5mls/kg/hr for 6-12 hours
- Stage 2: 2.0 – 2.9 times baseline
- UOP <0.5mls/kg/hr great than or equal to 12 hours
- Stage 3: 3.0 times baseline or greater than or equal to 4mg/dl
- UOP <0.3mls/kg/hr for greater than or equal to 24 hours OR anuric for 12 hours
- OR initiation of renal replacement therapy
- <18 years old GFR<35mls/min

CKD Stages

- Stage 1 Slightly diminished function: kidney damage with normal or relatively high GFR (≥90 ml/min/1.73 m²) and persistent albuminuria. Kidney damage is defined as pathological abnormalities or markers of damage, including abnormalities in blood or urine tests or imaging studies.
- Stage 2 Mild reduction in GFR (60–89 ml/min/1.73 m²) with kidney damage. Kidney damage is defined as pathological abnormalities or markers of damage, including abnormalities in blood or urine tests or imaging studies.
- Stage 3 Moderate reduction in GFR (30–59 ml/min/1.73 m²): British guidelines distinguish between stage 3A (GFR 45–59) and stage 3B (GFR 30–44) for purposes of screening and referral.
- Stage 4 Severe reduction in GFR (15–29 ml/min/1.73 m²): Preparation for renal replacement therapy.
- Stage 5 Established kidney failure (GFR <15 ml/min/1.73 m²). permanent renal replacement therapy., end-stage kidney disease
RIFLE

- The RIFLE criteria, proposed by the Acute Dialysis Quality Initiative (ADQI) group, aid in assessment of the severity of a person’s acute kidney injury. The acronym RIFLE is used to define the spectrum of progressive kidney injury seen in AKI
- Risk: 1.5-fold increase in the serum creatinine, or glomerular filtration rate (GFR) decrease by 25 percent, or urine output <0.5 mL/kg per hour for six hours.
- Injury: Two-fold increase in the serum creatinine, or GFR decrease by 50 percent, or urine output <0.5 mL/kg per hour for 12 hours.
- Failure: Three-fold increase in the serum creatinine, or GFR decrease by 75 percent, or urine output of <0.3 mL/kg per hour for 24 hours, or no urine output (anuria) for 12 hours.
- Loss: Complete loss of kidney function (e.g., need for renal replacement therapy) for more than four weeks.
- End-stage kidney disease: Complete loss of kidney function (e.g., need for renal replacement therapy) for more than three months.

CTCAE V4

- Consider CTCAE 4.0.
- Grade 1: Creatinine level increase of >0.3, or creatinine 1.5 – 2.0 above baseline.
- Grade 2: Creatinine 2-3 x above baseline.
- Grade 3: Creatinine >3 x above baseline or >4 mg/dl, hospitalization indicated.

- Therefore a baseline creatinine of 0.8 would need to rise to 1.6-2.4 before it was grade three in clinical trial work but would only need to be 1.2 to actually be AKI in nephrology.
- Is nephrotoxicity under reported?

Nephrotoxicity of Common Agents

- Ifosfamide
- Nature of Injury: Proximal tubular acidosis.
- Presentation: Fanconi syndrome, glucosuria with normoglycemia, renal phos, mag and potassium wasting, hypouricemia.
- Management: Limit dose, consider risk factors such as prior platinum therapy, prior renal irradiation, nephrectomy or other renal injury.

Advanced Practice (Hughes)
Nephrotoxicity of Common Agents

• Cisplatin
  • Nature of Injury: Tubular
  • Onset within 3 hours lasts up to two years.
  • Presentation: elevated serum creat, bland UA, minimal proteinuria
  • Magnesium wasting may be prolonged up to 6 years
  • Renal salt wasting may present late at 2-4 months after cisplatin
  • Intrinsic renal condition FeNa >3%
  • Muddy brown casts ATN
  • Management: aggressive hydration may reduce incidence, mannitol and loop diuretics no clear benefit, amifostine limited due to cost and concerns for diminished anti tumor effect.
  

• Methotrexate
  • Nature of Injury: direct precipitation only in doses higher than 1gm/m2
  • Presentation: oliguric or non oliguric AKI, bland UA, no proteinuria
  • Management: alkalize urine, aggressive hydration 2.5-3.5L/24 hours, avoid PCN, sulfisoxazole, NSAIDS may potentiate nephrotoxicity.
  • Leucovorin rescues until MTX level less than 100
  • Consider Glucarpidase but little evidence and only effects extracellular levels of methotrexate. Use only if standard therapies have failed. (Cavone JL, Yang D, Wang A. Glucarpidase intervention for delayed methotrexate clearance. Ann Pharmacother 48: 897-907, 2014)

• Gemcitabine
  • Nature of Injury: thrombotic microangiopathy
  • Presentation: new onset AKI, microangiopathic hemolytic anemia, new or worsening hypertension.
  • Management: withdraw drug, 28% complete recovery 48% partial or stable renal function
  • Options include plasmaphereses not shown to be better than conservative management
  • Eculizumab response is similar to supportive care alone. (Stark M, Vonderheide RH. Use of eculizumab in refractory gemcitabine-induced thrombotic microangiopathy. J Pain Symptom Manage 40: 894-898, 2014)
  (Teo HL, Gao E. Eculizumab therapy leads to rapid resolution of thrombocytopenia in drug induced hemolytic uremic syndrome. Ann intern Med 154: 206-213, 2014)
Nephrotoxicity of Common Agents

- Bevacizumab VEGF
- Nature of Injury: thrombotic microangiopathy
- Presentation: new or worsening hypertension, proteinuria, elevated creat, MAHA, low haptoglobin, high lactate dehydrogenase
- Management: before withdrawing drug consider that current evidence suggests HTN may be a marker of response, treat BP >140-90 or DBP >20mmHg above baseline
- Consider ACE/ARB if proteinuria
- Control BP and continue
- STOP for nephrotic syndrome, HTN with end organ damage, MAHA, renal insufficiency


Nephrotoxicity of Novel Agents

- Cetuximab
- Nature of Injury: Distal Convoluted Tubule
- Presentation: hypomagnesemia theory is that block EGFR in DCT leads to magnesium wasting.
- Severity of hypomagnesemia correlates to length of exposure to drug
- Management: DIFFICULT can require up to 6-10gms daily of IV magnesium but most cases resolved in 4 weeks after discontinuation of drug.
- Follow serum calcium, theory is that PTH resistance leads to hypocalcemia, will resolve as hypomagnesemia resolves


Nephrotoxicity of Novel Agents

- Imatinib (small molecule TKI)
- Nature of Injury: UNKNOWN thought to inhibit PDGFR
- Presentation: hypophosphatemia, theory is that this inhibits PDGFR leading to decreased calcium and phos efflux from bone, lower calcium egress leads to mild secondary hyperparathyroidism and increased renal phos losses.
- In one study 51% of patients developed hypophosphatemia, even pts with low and normal serum phos had elevated urine fractional excretion of phos.
- Only those with low serum phos had elevated PTH levels.
- Management prompt phos repletion

Nephrotoxicity of Novel Agents

- Ipilimumab CTLA-4 antibodies
- Fully human monoclonal antibody directed against cytotoxic T-lymphocyte antigen-4
- Nature of injury: immune mediated AKI, not common in kidney, but cases of granulomatous acute interstitial nephritis, and lupus nephritis have been reported.
- Presentation: AKI
- Management: Resolves with discontinuation of drug and steroids


Nephrotoxicity of Novel Agents

- Nivolumab PD1 - human programmed death receptor-1 (PD-1) inhibitor (PD-1L expressed on proximal tubular epithelial cells)
- Nature of injury: immune related
- Presentation: AKI, Acute Interstitial Nephritis
- Management: stop drug, steroids

• OPDIVO can cause immune-mediated nephritis. Monitor patients for increased serum creatinine prior to and periodically during treatment. Administer corticosteroids for Grades 2-4 increased serum creatinine. Withhold OPDIVO for Grade 2 or 3 and permanently discontinue for Grade 4 increased serum creatinine. In patients receiving OPDIVO monotherapy, immune-mediated nephritis and renal dysfunction occurred in 1.2% (23/1994) of patients. In patients receiving OPDIVO with YERVOY, immune-mediated nephritis and renal dysfunction occurred in 2.2% (4/407) of patients.

Case study Bevacizumab

71 year old female with ovarian cancer
This is a 70 year old white female with a PMH of HTN, ulcerative colitis, stage IV high grade serous ovarian carcinoma Avastin induced nephrotoxicity manifesting as TMA and refractory HTN on multiple agents.
Prior chemo includes carboplatin docetaxel May to October 2016
Bevacizumab/liposomal Doxorubicin March to September 2017
Admitted with Hypertensive urgency and TMA
Case study Nivolumab

69 year old male with GE junction tumor s/p PD1 inhibitor, stopped after two doses for AKI.

Creatinine from 1.3 to 3.7.

Renal biopsy showed diffuse active tubulointerstitial nephritis with focal granulomas

Case Study CART T

19 year old male with GCB DLBCL s/p CART T cell infusion

admitted to the ICU after cytokine release syndrome

Now with urine output of 10L in 24 hours

Summary

Novel therapies
Watch for early signs of AKI a small rise in serum creatinine may be important.
Nephrotoxicity may be under reported in novel therapies
Data is emerging every day
CAR-T?
The Role of Nurse Clinicians & Advanced Practice Providers in the Management of Supportive Oncology Needs and Treatment-Related Side Effects for Women with Gestational Trophoblastic Neoplasia

Nancy J. Anderson CNP, Karen Novak CNP, Sara Covert, RN, John R. Lurain MD
John I. Brewer Trophoblastic Disease Center
Robert H. Lurie Comprehensive Cancer Center
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Disclosures

• No Disclosures
Background

Women diagnosed with gestational trophoblastic neoplasia (GTN) have an excellent prognosis with cure rates approaching 100%.

Despite the fact that full recovery is generally expected, these women are confronted with:
- a potentially life-threatening diagnosis
- chemotherapy and/or surgical treatment
- a delay in future pregnancy


Psychosocial Stress

Women with GTN experience increased levels of anxiety, anger, sadness, as well as shifts in feelings of self esteem, marital relationships, and attitudes toward future pregnancies.

Women with metastatic disease receiving multagent chemotherapy are more likely to express emotional distress, physical problems, and concerns about fertility and pregnancy.

The emotional impact of GTN may be protracted and lingering, combined with the fear of another gestational trophoblastic event in future pregnancy.


Treatment-Related Side Effects

Women receiving single-agent methotrexate or actinomycin D for low-risk GTN may experience stomatitis, nausea, eye dryness, rash, or pleuritis.

Women receiving multagent chemotherapy (EMA-CO, EMA-EP, or platinum-containing regimens) for high-risk GTN experience alopecia, more fatigue and nausea, as well as occasional peripheral neuropathy and hearing loss.

Prevention strategies, early recognition, and appropriate intervention will result in minimization of toxicity, adherence to treatment, and improved quality of life.

Lurain JR. Expert Opin Pharmacother 2003; 4: 1-13
Background

- An important component of treatment success in GTN is to address supportive oncology needs as well as disease and treatment-related side effects.
- Patient education prior to and throughout treatment is most often the responsibility of advanced practice providers and nurse clinicians.

Objectives

To provide each patient with verbal and written disease and treatment-specific education as well as employ institutional resources before, during, and after treatment of GTN which will:

- decrease stress/anxiety
- promote patient confidence in their case
- increase compliance with treatment and follow-up
- improve overall quality of life

Materials & Methods

- We reviewed patient educational materials available from other major trophoblastic disease centers as well as our own.
- We analyzed evidence-based medicine regarding management of chemotherapy-related side effects.
- We incorporated our own experiences as well as standards of care published by ONS, ASCO, and NCCN.
Results
We developed a patient-directed, disease-specific educational binder regarding each GTN, chemotherapy treatment plan, nursing interventions for the management of treatment side effects, and supportive oncology resources, including psychological and oncofertility concerns, as well as standardized verbal communication tool.

GTN Educational Binder

- My treatment
  - Patient-specific diagnosis (postmolar GTN, low-risk GTN, high-risk GTN, PSTT, ETT)
  - Plan of care
    - Chemotherapy protocol
    - Surgery

- Personal Notes/Documents
  - space to write notes/questions or journal
  - section for Power of Attorney for Healthcare
GTN Educational Binder

Treatment Side Effects:
- Signs, symptoms, and management tips for:
  - Infection, fatigue, bleeding/clotting, nau-sa/vomiting, hair loss/thinning, eye disorders, dental complications
  - Nausea, vomiting, diarrhea, constipation, mood changes, sexual health, fertility

- Medication check lists for:
  - Preventing allergic reactions to chemotherapy agents
  - Constipation action plan
  - Pain management
  - Stomatitis prevention/treatment

Tests and Procedures:
- Labs and imaging results and how to interpret them

Patient Records:
- Section dedicated for patient to keep records of HCG levels, nursing discharge instructions, and incidental information

Schedule:
- Calendar for patients to keep track of appointments for clinic visits and chemotherapy

Supportive Resources Available at the Robert H. Lurie Comprehensive Cancer Center:
- Social worker
- Psychiatric service
- Nutrition services
- Fertility preservation program
- Financial services
- Support group / pastoral services / advance directive experts
- Care for the caregiver advice
GTN Educational Binder

Chemotherapy Regimens:
- Methotrexate
- Actinomycin D
- EMA-CO, EMA-EP
- BEP, VIP, ICE, TP/TE
- G-CSFs used to prevent neutropenia and treatment delays

Conclusions
Development of a patient-directed, disease specific booklet regarding each GTN, chemotherapy treatment plans, nursing interventions for the management of treatment related side effects, and supportive oncology resources:
- Improves patient outcomes
- Maintains consistency in treatment standards of care
- Diminishes patient anxiety related to treatment and outcomes
- Increases patient compliance with treatment and side effect management

Key Takeaways
- APPs and nurses play a key role in the education of Gestational Trophoblastic Neoplasia (GTN) patient’s on their disease, chemotherapy regimens, symptom management, and fertility navigation.
- An important component of treatment success in the GTN is to provide written and verbal disease and treatment-specific education as well as supportive oncology resources.
- An education booklet can decrease stress/anxiety, promote confidence in patient case, increase compliance with treatment and follow-up and especially improve overall quality of life.


Hepatitis B Screenings Prior to Initiation of Rituximab Treatment

Patricia Karwan DNP, APRN-BC

Introduction

WHY LOOK AT HEPATITIS B AND RITUXIMAB?

Hepatitis B Virus (HBV) reactivation has occurred in patients with prior HBV exposure who are later treated with drugs classified as CD20-directed cytolytic antibodies, including rituximab.

Some cases have resulted in fulminant hepatitis, hepatic failure, and death.
Disclosures
• Nothing to disclose

Objectives
1. To evaluate patients receiving rituximab to see if Hepatitis B titers are being checked prior to treatment initiation.
2. To evaluate if patients receiving rituximab that were tested, returned with a positive result—potentially changing treatment protocols.
3. To evaluate need of policy change to ensure Hepatitis B titers are checked prior to ordering treatment

Methods
Retrospective chart review:
Assessing documentation related to any screening for Hepatitis B prior to initiation of rituximab therapy

Inclusion criteria: 1. gender
2. age
3. oncology or non-oncology diagnosis
4. new patients seen in outpatient infusion unit that started treatment in 2016
Results
Characteristics noted in chart review from 2016:

- 45 patients - 44 patients over age of 40
- 31 females and 14 males

14 patients were screened for Hepatitis B prior to initiation of treatment (9 female, 5 male)

- 12 of 14 patients had oncologic diagnosis
- 18 patients with oncologic diagnosis
- 27 patients with non-oncologic diagnosis

1 patient converted to a positive Hepatitis B result after initiation of Rituximab
Conclusion
There is an increased need to monitor and screen patients receiving rituximab due to the potential re-activation of Hepatitis B for any patient with a prior exposure.

Data for 2016 showed that 12 of the 18 patients (67%) of patients with an oncology diagnosis were screened, but we still had 33% without screening.

Recommendations:
Policy change to promote the need for all patients (oncologic or non-oncologic) to be screened for Hepatitis B titers prior to initiation of rituximab for treatment.

Key Takeaways
- Hepatitis B reactivation has occurred with drugs classified as CD 20 directed cytolytic antibodies.
- Some of the drugs that are CD 20 directed antibodies include Rituximab.
- Hepatitis B screening should be performed prior to the administration of the commonly used drug Rituximab.
References


Self-care Support for Patients with Gastrointestinal Cancer: iCancerHealth Promoting

Nina Grenon, DNP, AOCN
Adult Geriatric Nurse Practitioner
Dana-Farber Cancer Institute

Disclosures

• “No commercial or financial interest to disclose”

Our Team

• Co-Investigators
  – Nadine J. McCleary, MD, MPH
  – Nina Grenon, DNP
• Principal Investigator
  – Donna L. Berry, PhD, RN, FAAN, AOCN
• Statistician
  – Traci Blonquist, MS
• Project Director
  – Manan Nayak, MA
• Research Staff
  – Tha’er Momani, PhD, RN
• Partial funding
  – Medocity, Inc.
What's Been Done Before?

- Standardized symptom and quality of life (SxQOL) assessments/interventions have been developed and used widely in research studies to measure outcomes of treatments and interventions.
- Clinical benefits:
  - Increase the depth and breadth of discussions of SxQOL and patient-reported emotional well-being during clinic visits.
  - Increase treatment of psychosocial issues and symptoms.
  - Reduce cancer symptom distress when combined with self care patient education and monitoring.
  - Lengthen survival in advanced stage patients.

Technology

- Patient-centered technologies have been developed and tested for both point of service and remote (home) use:
  - Computers
  - Tablets
  - Smart phones

What Do We Want to Learn?

- Can we add a direct patient-to-clinician messaging component?
- Which features of such a program are utilized most often?
- How often will patients use it?
- What do patients and clinicians think about it?
Participants

• Eligible patient participants were seen in gastrointestinal (GI) oncology clinic
  – 18 years or older
  – Any stage malignant gastrointestinal disease
  – Receiving or planning therapy with the GI oncology service
  – Speak and read English
  – Remote access via either a personal computer web browser, iOS device (smart phone or tablet), or Android (phone only)

Participants, cont.

• Patients were excluded from enrollment if they had a documented diagnosis of a psychiatric depressive or cognitive impairment
• Eligible clinician participants
  – Nurses, physicians or physician assistants
  – Performed consults/exams in the GI oncology clinic
• IRB approved minimal risk study

Study Design

• Design: Single arm, pilot study
• The purpose of the study was to explore implementation, feasibility and impact of the iCancerHealth® intervention
Study Procedures

• Participants engaged with the iCancerHealth® application (app) at home
• All participants registered and used the platform to complete the symptom assessment in clinic at baseline, either on a personal device or on a study iPad
• From home, participants reported symptoms, received management information tailored to level of symptom severity and communications from clinicians as needed

Study Procedures, cont.

• Clinicians received alerts and communication through the provider side (Medocity MD®) of the application
• Participants were called weekly, or met in person during a regular clinic visit, and reminded to use the app and finally, to perform a last symptom report 4-6 weeks after enrollment
A total of 70 patient participants were planned and a 15% attrition rate was expected. With 60 evaluable patient participants and complete T1-T2 data, the 95% Confidence Interval (CI) was planned to be no wider than 26%.

With 60 evaluable participants, we needed to observe 13 accessing iCancerHealth to have the upper bound of the 95% CI covering 34% (previous study unprompted access rate). Therefore, iCancerHealth will be considered feasible if at least an 80% enrollment rate is observed and at least 13 of 60 patients remotely access the tool.

A total of 64 patients were approached to participate in the study, of which 57 enrolled.

Two participants withdrew on the day of the final T2, declining the final symptom assessment and acceptability survey. Of the remaining 55, four participants chose not to respond to the final survey, stating they had not used the app sufficiently at home to answer the acceptability survey.
Participant Demographics

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Technology Use Demographics

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Results, cont.

• If a participant entered at least 1 module (calendar, community, dashboard, health tracker, medical diary, inbox, medications, profile, nutrition, scrapbook, or settings), then that access was considered remote use.

• 53 (93%; 95% exact CI 85-99%) accessed at least 1 feature, at least once.
Results, cont.

- Favorite feature of the application?
  - Patient-clinician communication function (n=10)
  - Symptom tracking function (n=9)
  - Daily medication reminder (n=5)
  - Information about side effects (n=2)
  - Medical diary (n=2)
  - Monitor trends (n=2)
  - Pill box (n=1)
  - Community forum (n=1)

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Acceptability Details

The proportion of 51 participants indicating >4 on core acceptability items at T2

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<tr>
<td>Satisfaction</td>
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</table>

*Percentage of those answering these items
†Indicate those participants who used both version 1 and 2 and both

Was This Acceptable?

**Patient Participants**
- The overall median E-acceptability scale score (easy, understandable, enjoy, helpful, amount of time, and satisfaction) was 25.5 (range 12-30; maximum possible 30)

**Clinician Participants**
- All clinicians accessed the following features at least once after enrollment and orientation: community, dashboard, inbox, medication and health alerts, my inbox, my profile, and participant dashboard
- Two of the three clinicians accessed: participant record, settings, and symptom management
- One of the clinicians viewed the medical diary
Clinician Comments

- Ease of use, visuals easy to understand
- Direct emails were helpful at expanding care
- Requires integration in EMR

Study Limitations

- Single arm study
- Limited to one disease center (gastrointestinal cancer center)
- Small sample of providers

Conclusion

In a sample of patients actively undergoing treatment for gastrointestinal cancer, and who had Internet access on a personal device, we found a high percentage of remote users and adequate acceptability with the iCancerHealth® application. Our criteria for patient participant success in this pilot study were met. Clinician users were satisfied with most aspects of the app.
Key Takeaways

- The technology is feasible, it can educate patients to become more confident and empower self management of symptoms.
- The technology needs to be embedded within specific electronic medical records.
- The technology needs testing in the elderly and other high risk population

References


References, cont.