Mantle Cell Lymphoma (MCL)

PATHOLOGIC DIAGNOSIS

ESSENTIAL:

- Hematopathology review of all slides with at least one tumor paraffin block. Hematopathology confirmation of classic versus aggressive variant of MCL (blastoid/pleomorphic). Re-biopsy if consult material is non-diagnostic.
- Adequate immunophenotype to confirm diagnosis[1]
  - Paraffin panel:
    - Pan B-cell marker (CD19, CD20, PAX5), CD3, CD5, CD10, and cyclin D1
    - Ki-67 (proliferation rate)

    or
  - Flow cytometry immunophenotyping: kappa/lambda light chains, CD5, CD10, CD19, CD20, CD23, FMC-7, CD200, and CD43

OF USE IN CERTAIN CIRCUMSTANCES:

- Molecular genetic analysis
  - Somatic hyper-mutation for IGHV gene rearrangement and mutation status
  - *TP53*
  - *NSD2*[2]
  - *CDKN2A*[3]
  - *NOTCH1*
  - *BTK*
  - *KMT2D*[3]
  - *NOTCH2*[2]
- Immunohistochemistry for *SOX-11*[2]
- FISH to detect t(11;14)(q13;q32)/*CCND1-IgH, TP53*, and *MYC*

STRONGLY RECOMMENDED:

- Fine needle aspiration (FNA) or core biopsy for tissue banking by protocol

INITIAL EVALUATION

ESSENTIAL:

- Physical exam: attention to node-bearing areas, including Waldeyer's ring, size of liver and spleen, and patient's age
- Performance status (ECOG)
- B symptoms (fever, drenching night sweats, unintentional weight loss)
- CBC with differential, LDH, BUN, creatinine, albumin, AST, total bilirubin, alkaline phosphatase, serum calcium, uric acid
- Screening for HIV 1 and 2, hepatitis B and C (HBcAb, HBaAg, HCVAb)
- Beta-2 microglobulin (B2M)
- Chest x-ray, PA and lateral
- Bone marrow bilateral biopsy with unilateral aspirate
- CT neck, chest, abdomen and pelvis with contrast
- PET/CT without contrast
- Lifestyle risk assessment[4]

OF USE IN SELECTED CASES:

- Upper GI/barium enema/endoscopy
- Plain bone radiographs and bone scan
- CT head or MRI brain
- Discuss fertility preservation options and sperm banking for patients of child bearing potential
- Lumbar puncture
- Stool guaiac
- Colonoscopy
- Urine pregnancy test
- Referral(s) as indicated:
  - Cardiology to screen for cardiac related comorbidities
  - Genetics to screen for family history of hematologic or other cancers
  - Dermatology to screen for secondary cancer risk

Induction Therapy for untreated MCL see Page 2

FISH = fluorescence in situ hybridization

[1] Immunophenotype: CD5+, CD20+, CD43+, CD23-/+, cyclin D1+. **Note**: Some cases of Mantle Cell Lymphoma may be CD5-, CD10+, or CD23+. If the diagnosis is suspected, cyclin D1 staining or FISH to demonstrate t(11;14)(q13;q32) should be performed.

[2] Approved by internal Molecular Testing Evaluation Committee (MTEC) for Mantle Cell Lymphoma but currently not available for on-site testing

[3] Currently not approved by MTEC and not available for on-site testing

[4] See Physical Activity, Nutrition, and Tobacco Cessation algorithms; ongoing reassessment of lifestyle risks should be a part of routine clinical practice

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Mantle Cell Lymphoma (MCL)

Note: Consider Clinical Trials as treatment options for eligible patients.

PRESENTATION

Untreated MCL

MD Anderson high risk factors[1] present?

- Yes → Age less than or equal to 65?
  - Yes →
    - Clinical trial
    - Window-1 regimen[2] (off-protocol)
    - R-HCVAD/R-MA[2]
    - R-CHOP[2] **and/or** radiation therapy if early Stage I or II
    - R-bendamustine with radiation therapy if early Stage I or II
    - R-CHOP/R-DHAP[2] **or** R-HCVAD/R-MA[2] followed by autologous stem cell transplant
    - Lenalidomide with rituximab
  - No →
    - Clinical trial
    - R-CHOP[2] with or without maintenance rituximab every 2 months **and/or** radiation therapy if early Stage I or II
    - R-bendamustine with or without maintenance rituximab every 2 months **and/or** radiation therapy if early Stage I or II
    - Ibrutinib with rituximab
    - Lenalidomide with rituximab
    - R-BAC[1]
- No → See Page 3 for patients with no or low risk factors

INITIAL THERAPY

FOLLOW-UP

Follow-up:

- Year 1: Every 3 months
  - CBC with differential, complete metabolic panel (CMP), LDH, Beta-2 microglobulin (B2M), and other labs as clinically indicated
  - CT chest, abdomen, and pelvis or PET/CT (if feasible) until negative or clinically indicated
  - Unilateral bone marrow biopsy and aspiration until negative or clinically indicated
- Years 2 and 3: Every 4 months
  - CBC with differential, CMP, LDH, B2M, and other clinically warranted labs
  - CT chest, abdomen, and pelvis or PET/CT (if feasible) until negative or clinically indicated
- Years 4 and 5: Every 6 months
  - CBC with differential, CMP, LDH, B2M, and other clinically warranted labs
  - CT chest, abdomen, and pelvis or PET/CT (if feasible) until negative or clinically indicated
- After years 5: Annually
  - CBC with differential, CMP, LDH, B2M, and other labs as clinically indicated
  - CT chest, abdomen, and pelvis or PET/CT (if feasible) until negative or clinically indicated
- GI colonoscopy and upper GI endoscopy with random biopsies (if initially involved or if clinically indicated), every 6 months until negative results

→ Relapsed or refractory MCL, see Page 4

[1] High Risk factors: Blastoid/pleomorphic histology, *TP53* mutation or *del17p* by FISH, complex karyotype, MYC positive by FISH, bulky tumor > 7 cm and spleen > 20 cm, Ki-67 ≥ 30% in tissue biopsy

[2] Chemotherapy regimen abbreviations, see Appendix A

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Mantle Cell Lymphoma (MCL)

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PRESENTATION

Patient with no or low risk factors

Age less than or equal to 65?

INITIAL THERAPY

Yes

- Clinical trial
- Window-1 regimen[1] (off-protocol)
- R-HCVAD/R-MA[1]
- R-CHOP[1] **and/or** radiation therapy if early Stage I or II
- R-bendamustine with radiation therapy if early Stage I or II
- R-CHOP/R-DHAP[1] **or** R-HCVAD/R-MA[1] followed by autologous stem cell transplant
- Lenalidomide with rituximab
- Ibrutinib with rituximab
- Rituximab single agent
- Observation

No

- Clinical trial
- R-CHOP[1] with or without maintenance rituximab every 2 months **and/or** radiation therapy if early Stage I or II
- R-bendamustine with or without maintenance rituximab every 2 months **and/or** radiation therapy if early Stage I or II
- Ibrutinib with rituximab
- Lenalidomide with rituximab
- R-BAC[1]
- Rituximab single agent
- Observation

FOLLOW-UP

Follow-up:

- Year 1: Every 3 months
  - CBC with differential, complete metabolic panel (CMP), LDH, Beta-2 microglobulin (B2M), and other labs as clinically indicated
  - CT chest, abdomen, and pelvis or PET/CT (if feasible) until negative or clinically indicated
  - Unilateral bone marrow biopsy and aspiration until negative or clinically indicated
- Years 2 and 3: Every 4 months
  - CBC with differential, CMP, LDH, B2M, and other clinically warranted labs
  - CT chest, abdomen, and pelvis or PET/CT (if feasible) until negative or clinically indicated
- Years 4 and 5: Every 6 months
  - CBC with differential, CMP, LDH, B2M, and other clinically warranted labs
  - CT chest, abdomen, and pelvis or PET/CT (if feasible) until negative or clinically indicated
- After years 5: Annually
  - CBC with differential, CMP, LDH, B2M, and other labs as clinically indicated
  - CT chest, abdomen, and pelvis or PET/CT (if feasible) until negative or clinically indicated
- GI colonoscopy and upper GI endoscopy with random biopsies (if initially involved or if clinically indicated), every 6 months until negative results

Relapsed or refractory MCL, see Page 4

[1] Chemotherapy regimen abbreviations, see Appendix A

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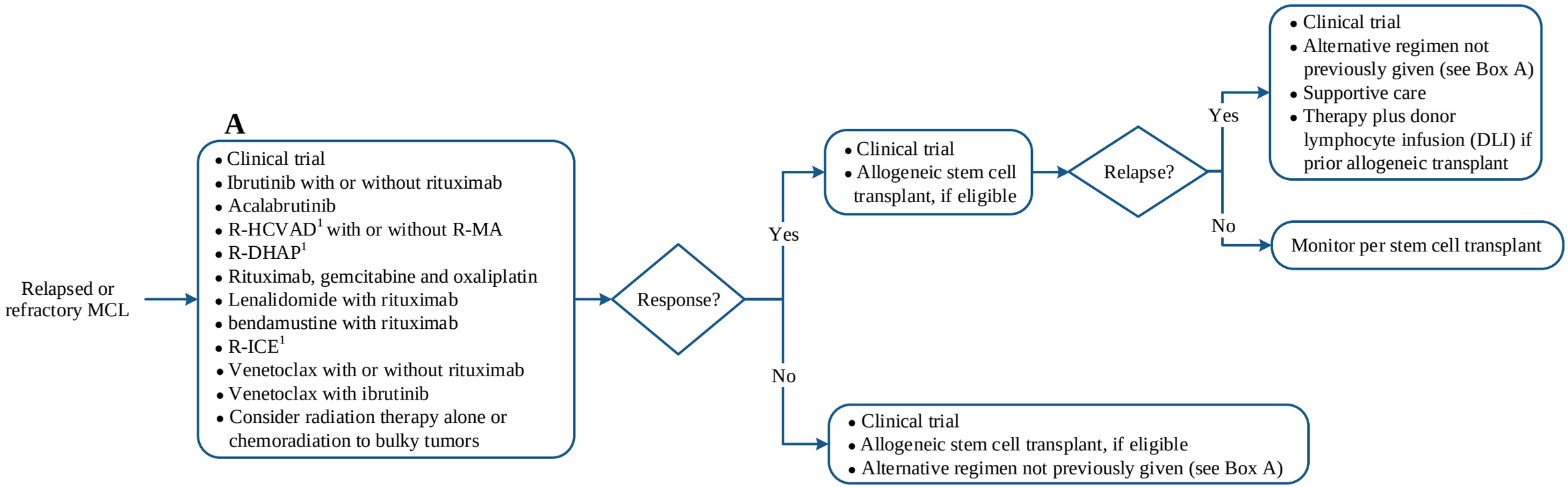
Mantle Cell Lymphoma (MCL)

Note: Consider Clinical Trials as treatment options for eligible patients.

TREATMENT



[1] Chemotherapy regimen abbreviations, see Appendix A

APPENDIX A: Chemotherapy Regimen Abbreviations

Window-1: ibrutinib and rituximab followed by 4 cycles of R-HCVAD alternating with methotrexate and cytarabine
R-HCVAD/R-MA: rituximab, cyclophosphamide, mesna, doxorubicin, and vincristine; alternating with rituximab, methotrexate, and cytarabine
R-CHOP: rituximab, cyclophosphamide, doxorobucin, vincristine, and prednisone
R-DHAP: rituximab, cisplatin, cytarabine, and dexamethasone
R-BAC: rituximab, bendamustine, and low-dose cytarabine
R-ICE: rituximab, ifosfomide, etoposide, and carboplatin

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