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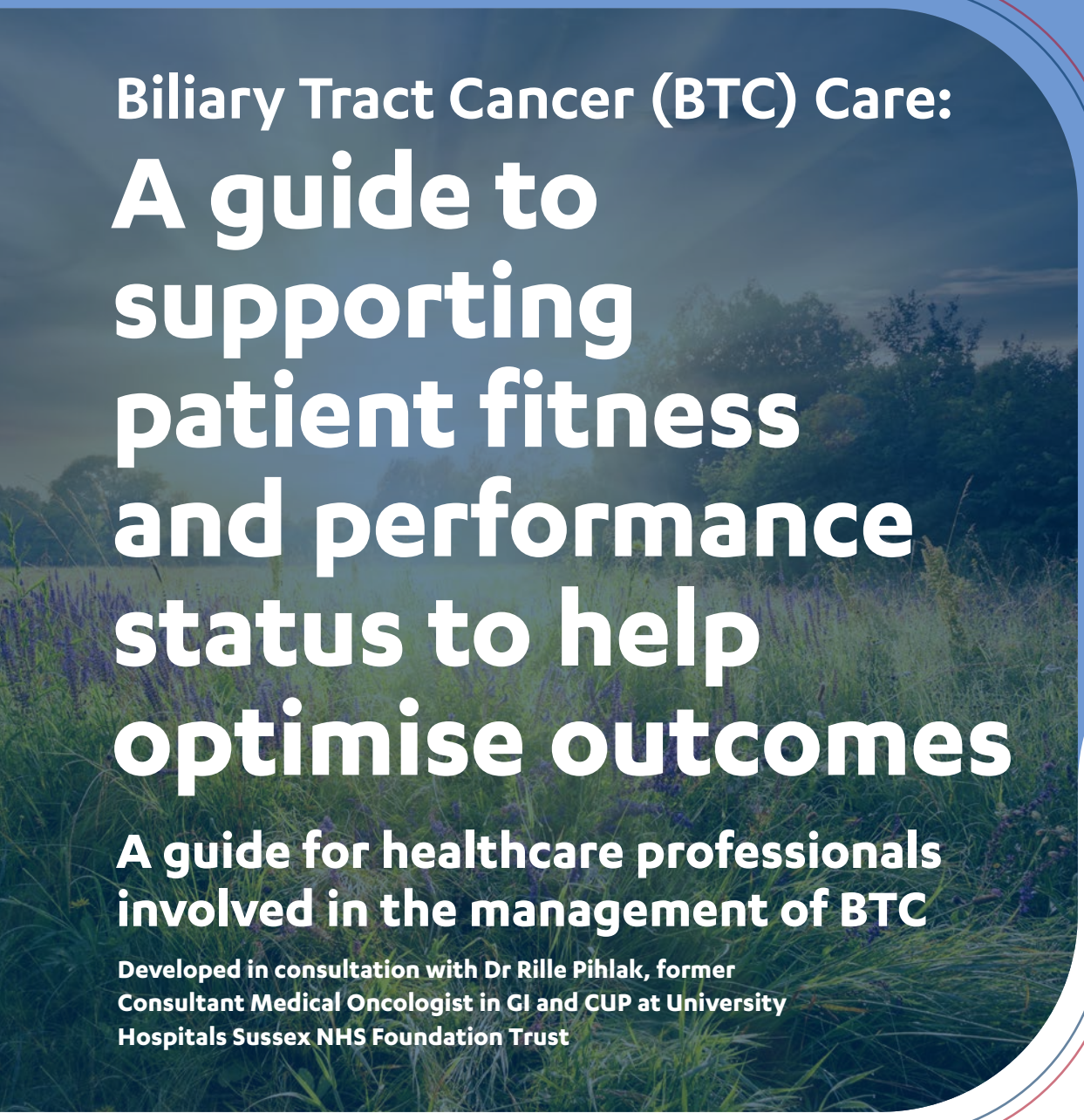
IMFINZI®
durvalumab
Injection for Intravenous Use 50 mg/mL



Biliary Tract Cancer (BTC) Care:

A guide to supporting patient fitness and performance status to help optimise outcomes

A guide for healthcare professionals involved in the management of BTC

Developed in consultation with Dr Rille Pihlak, former Consultant Medical Oncologist in GI and CUP at University Hospitals Sussex NHS Foundation Trust

Click or scan the QR code for UK IMFINZI prescribing information

Indication: IMFINZI (durvalumab) in combination with gemcitabine and cisplatin is indicated for the first-line treatment of adults with locally advanced, unresectable, or metastatic biliary tract cancer.[1]

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Introduction

Biliary tract cancer (BTC), also known as cholangiocarcinoma, is a **group of aggressive malignancies arising from the gallbladder or the biliary tree** and are **associated with a poor prognosis** due to most patients presenting with locally advanced or metastatic disease where the tumour is incurable.[2-3]

Up to 85% of people with BTCs present with advanced disease, at which point prognosis is poor, curative surgery is not feasible, and the **5-year survival rate is ~3–13%.**[5]

The management of BTC has evolved in recent years.[3] Notably, the **addition of immunotherapy to gemcitabine and cisplatin represents the standard of care**, while the increasing use of molecular profiling is driving advances in targeted therapies.[6-8]

While these advances in available treatment options are providing more treatment options for patients with BTC, optimising eligibility and patient outcomes also requires a coordinated, multidisciplinary team (MDT) approach that integrates timely diagnosis, accurate staging and personalised treatment planning. **Clear and established diagnostic pathways are also essential** to support earlier identification and appropriate referral of patients presenting with jaundice or other non-specific symptoms.[4,6]

Eastern Cooperative Oncology Performance Status (ECOG PS)

For many BTC systemic treatments, patients require a PS score of 0-1 to be eligible for treatment:

ECOG-PS Grade	Recommended treatment approach and eligibility
PS 0-1	Eligible for full range of available treatment options[1,3] The combination of durvalumab plus gemcitabine-cisplatin should be considered first line[2,5,6]
PS 2	Gemcitabine monotherapy* is recommended by BSG and ESMO guidelines in patients with reduced performance or other factors of fragility who are at risk of toxicity from platinum-containing chemotherapy regimens[2,6,8] *Gemcitabine is not licensed as a monotherapy for the treatment of BTC, please refer to the SmPC for full prescribing information.
PS 3-4	Palliative care may be more appropriate in patients with very poor performance status[6]

When assessing a patient's eligibility for treatment based on their ECOG performance status, it is important to note that **performance status can fluctuate over time** and that each assessment only provides a snapshot.[9] **Periodic reassessment of ECOG-PS may therefore be valuable**, as a patient who appears unwell on the day of review may be referred to palliative care, while an improvement at a later visit could mean that they are considered for more intensive treatment.[10]

While ECOG-PS is an important factor in guiding treatment decisions, the management of patients with BTC is complex and **treatment decisions should also be driven by MDT discussions as well as the patient's eligibility, priorities and preferences for care.**[4,6]

BSG guidelines recommend that the management of patients with BTC should be led by centres of expertise, while supporting local care where possible without compromising the need for specialist input.[6]

Managing symptoms to support treatment eligibility

Patients with BTC often experience a **high-symptom burden** with frequently reported symptoms including jaundice, abdominal pain, pruritus, nausea, unintentional weight loss, fever, and fatigue. These **symptoms can impair performance status,** therefore, limiting the patient's ability to tolerate treatment.[11]

Early and effective symptom management has the potential to improve quality of life, but can also help support eligibility for more intensive treatment options that may improve survival outcomes.[6,11]

Managing symptoms in patients with BTC requires detailed history taking to understand the nature and severity of symptoms as well as the underlying cause, whether they are disease- or treatment-related. Management should include both pharmacological and non-pharmacological approaches, supported by appropriate psychosocial care. **Coordinated care involving specialties across the MDT, including palliative care specialists, is essential to support effective symptom management** and holistic, patient-centred care.[6]

Early involvement of palliative and supportive care services, both locally and within specialist centres, can provide valuable support in managing symptoms and maintaining patient wellbeing and treatment readiness: [6,11]

Symptom	ESMO-recommended therapeutic approach*
Pain[12]	**Mild Pain (1-3 NRS):** NSAIDs or Paracetamol; reassess pain regularly. **Mild to moderate pain (4-6 NRS):** Weak opioids ± NSAIDs/Paracetamol; reassess pain regularly; use rescue medications. **Moderate to severe pain (7-10 NRS):** Strong opioids ± NSAIDs/ Paracetamol; increase dose if "end of dose failure" occurs, unless side effects develop. **If pain persists:** Reassess pain and treatment (pharmacological & non-pharmacological); consider invasive interventions with team decision. **If side effects develop:** Switch opioid or route of administration; use equianalgesic dose. Options include: • Oral or transdermal long-acting opioid • Systemic treatment **Always use rescue doses to treat BTcP.**
Fatigue[13]	Prior to management, all associated elements and contributing factors identified during diagnostic assessment (e.g., anaemia, pain, electrolyte disturbance, emotional distress, comorbidities, appetite loss and rapid weight loss) must be managed and followed by fatigue re-screening. **Management approaches:** • Patient and family education • Physical activity • Psychosocial interventions • Pharmacological options (e.g., corticosteroids such as dexamethasone or methylprednisolone) After a specific intervention on fatigue, patients must be re-evaluated.

Symptom	ESMO-recommended therapeutic approach*
Diarrhoea[14]	**Prior to management, conduct a medical history (including exposure to possible causative factors) and perform a physical examination.** **Possible causative factors include:** • Antineoplastic agent (e.g., chemotherapy or IO) • Other medications (e.g., antibiotic) • Infective agent • Bile salt malabsorption • Pancreatic insufficiency • Small intestine bacterial overgrowth **Uncomplicated diarrhoea:** • Oral hydration • Dietary modification • Loperamide (4 mg initially, then 2 mg after each loose stool to maximum of 16 mg/day)† • Avoid skin irritation • Notify treating physician **Complicated diarrhoea (e.g., fluid depletion, vomiting, fever)** • Loperamide (per dosing schedule above) + i.v. fluids and electrolytes. Other opioids, such as codeine can also be used. • Stool evaluation: blood and stool microbiology testing (e.g., Clostridium difficile, Salmonella, Campylobacter and other causes of infectious colitis) • Daily evaluation of CBC, electrolytes & urinary output • If treatment with loperamide or codeine does not work, consider octreotide (s.c. 100–150 µg tid or i.v. 25–50 µg tid; escalate to 500 µg tid if needed)‡ • Consider antibiotics if thought to be infective causes or small intestine bacterial overgrowth (fluoroquinolones, metronidazole, broad spectrum)

Symptom	ESMO-recommended therapeutic approach*
Chemotherapy/ Radiotherapy induced nausea and vomiting (R/CINV)[15]	Management should be based on the emetic risk of the chemotherapy or radiotherapy regimen, along with individual patient risk factors. Patients should be stratified by risk receive the recommended antiemetic regimen. **Please refer to the MASCC/ESMO 2023 guidelines for full details.** Persistent cancer or treatment related nausea and vomiting can contribute to weight loss and cachexia. Therefore, proactive assessment and early management are essential, particularly when treatments with a high risk of inducing malnutrition (such as combined-modality therapy, high-dose chemotherapy, or highly emetogenic agents) are planned, and prophylactic nutritional support should be considered.[16]
Cancer-related cachexia[16]	• **Screening for cachexia** should be integrated into routine cancer care, alongside immediate access to cachexia care interventions where required • Cachexia **care should be provided through an integrated approach** that combines nutrition, physical activity, psychological support, and involving palliative care and oncological expertise. • **Please consult the ESMO Clinical Practice Guidelines for detailed recommendations.**

*Please refer to respective SmPC of each medication for further details on indication and posology prior to prescribing.

†Loperamide is recommended at a maximum dosage of 12mg/day, please see SmPC for full information.[17]

‡Octreotide is recommended at 0.05 mg once or twice daily by s.c. injection, and on tolerability, dosage can be gradually increased to 0.1 to 0.2 mg 3 times daily. Please see the SmPC for full information.[18]

Bilirubin levels and bile duct stenting

Why are bilirubin levels important?

Over 90% of patients with extrahepatic BTC present with jaundice, due to biliary obstruction.[11]

Elevated bilirubin levels (hyperbilirubinemia) can delay the initiation of systemic treatments. **Biliary obstruction is a potentially life-threatening condition that must be resolved prior to starting treatment and, if it occurs during treatment, requires urgent management as an emergency.** Many chemotherapy agents, including gemcitabine, require intact mechanisms of bilirubin excretion and bile drainage to minimise the risk of drug toxicity. As gemcitabine forms the backbone of some 1L treatments for BTC, without treatment, patients with elevated bilirubin levels may not be eligible for more recently available treatments.[3,6,19,20]

Systemic therapies often require stringent bilirubin thresholds that must be achieved before treatment initiation. **A bilirubin level of ≤1.5 ULN is typically required for more recently available systemic therapies** depending on the regimen.[1,21]

The role of stenting in BTC management

Relief of biliary obstruction through stenting is crucial in extending patients survival and managing many symptoms associated with biliary obstruction, which can be life threatening, including abnormal liver function tests, abdominal pain, fatigue, weight loss, and acute cholangitis. Resolving biliary obstruction can help improve patient performance status, reverse other symptoms and therefore help improve eligibility for available therapies.[6,11]

The BSG guidelines strongly recommend that all centres managing patients with BTC have **established diagnostic pathways for patients presenting with jaundice or biliary obstruction,** with streamlined transition to local and regional hepato-pancreato-biliary (HPB) MDT meetings.[6]

Recommended stenting approaches for biliary obstruction:

Endoscopic retrograde cholangiopancreatography (ERCP) is the preferred approach for bile duct stenting, particularly in patients with poor performance status.[11]

If biliary access cannot be achieved by ERCP, alternative approaches include **endoscopic ultrasound (EUS)** guided biliary drainage or **percutaneous transhepatic cholangiography (PTC)**. While EUS has a lower complication rate compared to PTC, the choice of modality will likely be driven by anatomy, local availability and MDT discussions.[6]

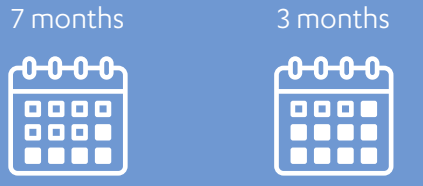
Stenting should only be carried out by gastroenterologists/endoscopists or interventional radiologists who are experienced in biliary stenting.[6]

See page 13 to learn more about the role of the MDT in managing complex cases.

Metal vs plastic stents: clinical considerations and guideline support

UK and EU guidelines recommend the use of metal stents, particularly in patients with a life expectancy exceeding 3 months.[2,6] Compared with plastic stents, they have lower rates of dysfunction, reintervention rates, improved survival outcomes and offer longer patency.[6,11] This makes metal stents more suitable for patients with improved life expectancy due to recently available therapies and when treatment (e.g., chemotherapy) is continuous, as there is limited opportunity to remove or replace plastic stents.[6]

Plastic biliary stents typically require replacement every 3 months due to higher occlusion rates, whereas metal stents remain patent for around 7 months.[11]



Monitoring and managing risks after biliary stenting

The rate of bilirubin normalisation after biliary stenting is dependent on initial bilirubin levels, but can occur quickly and positively impact a patient's PS:[19]

Initial bilirubin levels	Potential timeframe for normalisation*
≥171umol/L	Within 6 weeks
< 171umol/L	Within 3 weeks

*A downward trend or normalisation of bilirubin levels may be observed before 6 weeks; regular monitoring is recommended.

However, **it is important to continue to monitor a patient's overall health,** as although ERCP is a relatively routine procedure, there are **several serious complications to be aware of, in addition to stent blockage.** These include:[6]

- Cholangitis
- Pancreatitis
- Cyst duct obstruction
- Cholecystitis

Following stenting, patients should have a clear monitoring pathway to support early detection of recurrent stent blockage and on-demand endoscopic intervention. Regular liver function tests should continue during active oncology treatment or palliative follow-up to allow timely intervention if levels rise, indicating possible stent blockage.[6]

Patients should be given support phone numbers to call if they begin to identify signs of jaundice. **They should also have access to a home supply of antibiotics,** with instructions on when to use them if they develop stent cholangitis.[6] These measures can help to address problems quickly and may reduce the risk of serious complications.

If a **stent blockage is suspected, repeat cross-sectional imaging** is generally recommended to confirm the need for or possibility of further drainage (ERCP/EUS/PTC) and assess current anatomy. Decision of further management should be made in conjunction with the patient's wishes and performance status.[6]

Best practice in BTC molecular testing

The diagnostic pathway for BTC has changed significantly in recent years due to the growing availability of additional targeted therapeutic options.[2,3,6]

Molecular profiling has found that BTCs are target-rich malignancies, with actionable genetic alterations present in ~50% patients.[8]

As a result, **molecular profiling is recommended for patients with BTC** within the NHS. It should be carried out at the earliest opportunity, preferably before first-line therapy, with results and treatment options reviewed by clinicians with appropriate expertise to ensure patients receive the most appropriate treatment for their condition.[2,6,22] If required, seek advice from a specialist centre.

To ensure that sufficient tissue is collected for molecular testing, brush cytology alone should be avoided due to its limited sensitivity.[6] Where possible, **stenting procedures such as ERCP and PCT should be combined with biopsy to obtain adequate tissue for diagnostic pathology and molecular profiling.**[2]

The role of the MDT in managing complex cases

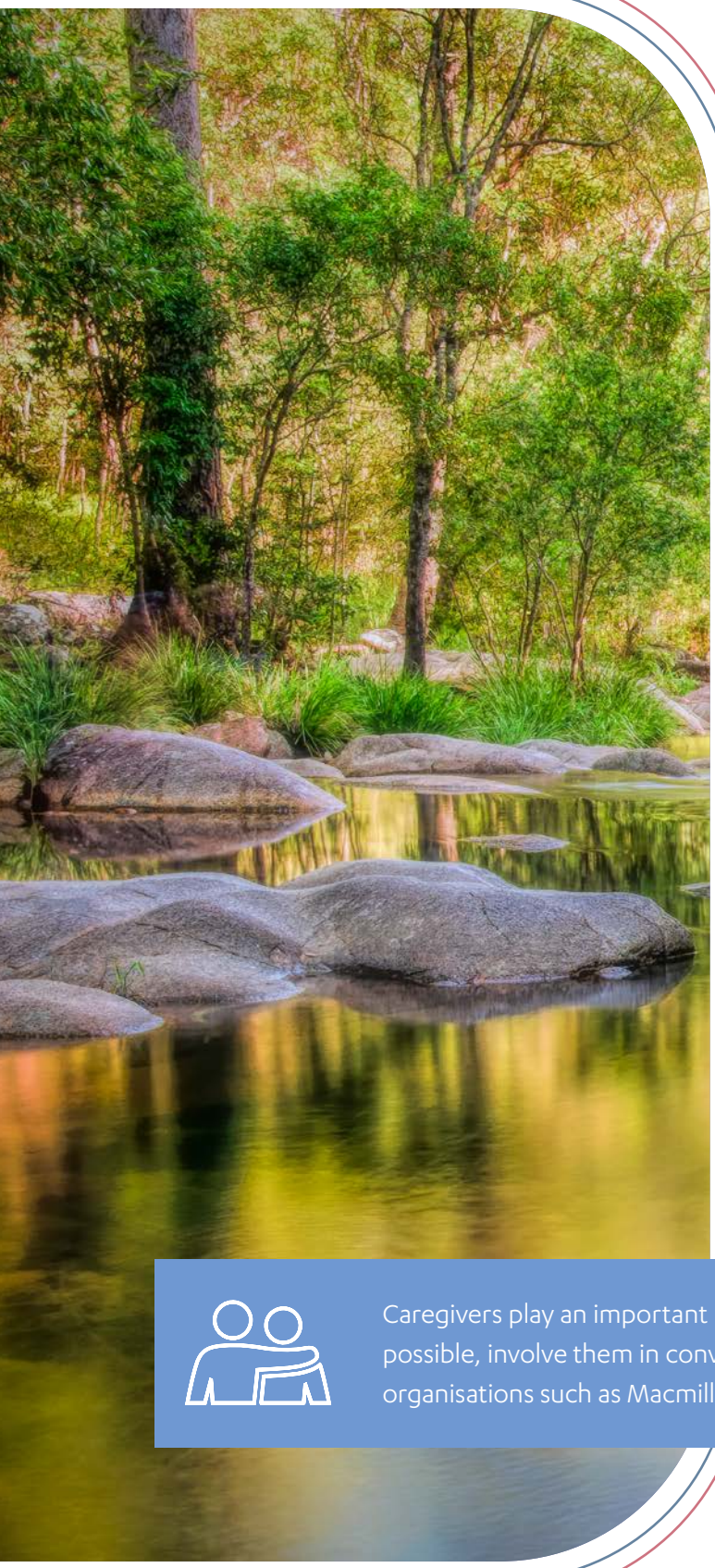
BTC is often diagnosed at an advanced stage, and management can be complex, with diagnostic and treatment decisions requiring input from a range of specialties. **Regular MDT meetings are key to supporting accurate staging, ensuring patients receive timely and appropriate treatment** and helping to anticipate and manage potential risks associated with treatment.[4]

The European Network for the Study of Cholangiocarcinoma (ENS-CCA) have developed guidelines for effective BTC MDTs:[4]

Mandatory specialists	Presence of the **oncologist, clinician** responsible for the patient's care, **surgeon**, diagnostic and interventional **radiologist, hepatologist, pathologist, endoscopist and gastroenterologist** should be **mandatory in a well-functioning MDT**
Desirable specialists	Presence of **palliative, nurse and dietitian**, basic researcher, psychologist and social worker should be recommended

Table adapted from Casadio M, et al. 2022.[4]

Addressing patient and caregiver concerns around treatment



A diagnosis of BTC can be overwhelming for patients and their families. **Clear, compassionate communication** from the outset is essential to **building trust, supporting informed decision-making and reducing anxiety.** Access to a HPB cancer nurse specialist can offer patients and their families valuable support and expertise, including early conversations about procedures to help them feel more informed and prepared for what's ahead.[6]

Additionally MDT discussions should consider patient preferences and supportive care needs to ensure they receive the treatment that's right for them, as **shared decision-making is central to patient-centred care.**[4] For patients offered systemic therapy, a consultant and/or clinical nurse specialist should communicate the potential **benefits, risks and impact on quality of life, and provide contact details and guidance** on what to do if they have worrying side-effects or symptoms.[6]

Palliative care also plays a pivotal role in supporting patients and provides support in key areas including psychological, social, cultural and spiritual wellbeing and helping patients understand their illness and treatment goals. They are important partners in BTC treatment planning and provide ongoing support, complementary to active treatment.[6,11]

Caregivers play an important role in supporting patients with BTC. Where possible, involve them in conversations and direct them to trusted support organisations such as Macmillan Cancer Support and AMMF.

The impact on emotional wellbeing on treatment decisions and outcomes

High levels of anxiety, depression and social isolation are commonly reported, with ~3 in 4 patients with BTC reporting symptoms of depression that impact their daily life, and nearly half reporting these symptoms as severe.[6,23]

This emotional distress can influence how patients engage with treatment, affecting decision making, appetite and food intake. This is particularly important in this patient group who are already at risk of malnutrition and muscle loss.[24]

Recognising and addressing these issues early is important. **Early palliative care has been associated with improved quality of life and lower rates of depression in patients with advanced cancer** when compared to standard of care in patients with advanced cancers.[11] Increased integration of psychological and supportive care into the multidisciplinary management of BTC may help ensure a more holistic patient-centred approach.[4]

Where appropriate **every person diagnosed with cancer should have access to personalised care, based on holistic needs assessment** completed by a CNS to ensure that their physical, practical, emotional and social needs are identified and addressed at the earliest opportunity. Additionally, **patients can be referred to services or signposted to information and support** that is available in their community and from charities.[25]

Signposting patients and their families to additional **support from organisations** such as AMMF, Macmillan Cancer Support, Maggies centres and PSC Support UK can also provide patients and their families with an **important source of information, reassurance and emotional support.**[6]

Visit our resource hub to download a patient support booklet you can share with your patients. It offers **practical relaxation techniques to help patients manage stress and improve their emotional well-being.** Click or scan the QR code below to access this booklet.

The role of nutrition in supporting immune health, strength and treatment tolerance

Nutrition is an important part of holistic BTC management and can support physical strength, and treatment tolerance and immune function.[24] The aggressive nature of BTC, along with its symptoms and treatment side-effects can often lead to weight loss, muscle wasting, and impaired metabolic function.[24] One meta-analysis study reported **that 46% of patients diagnosed with BTC experienced sarcopenia.**[26]

These changes can negatively impact quality of life, performance status and treatment tolerance, but may be improved through timely and appropriate nutritional interventions.[24] **Routine nutritional screening should be a routine part of BTC patient care**, with evidence-based dietary advice provided before, during and after cancer treatment.[24]

Where nutrition risk is identified, patients should receive a full nutrition assessment from a registered **dietitian, who can develop a personalised nutrition care plan in line with their medical management** and planned cancer treatment.[24] Access to a dietician or nutritionist is especially important for patients with BTC who are experiencing symptoms and difficulties with diet and digestion, such as bile acid malabsorption and small intestinal bacterial overgrowth.[4,6]

In patients with cancer who are receiving therapy or with an expected survival of at least a few months, **ensuring an adequate energy and nutrient intake is vital.** In patients who cannot eat adequate amounts of food, nutritional support should be provided as an essential component of hoistic care to improve food intake, weight and quality of life. Support should involve **dietary counselling, guidance on choosing high energy, high-protein foods, enriching foods** (e.g. by adding fat/oils, protein powder) and use of **oral nutritional supplements**.[16]

The goal is to ensure adequate intake of energy and nutrients by enabling the patient to eat normal food, enjoy eating and participate in meals with others as a component of social life.[16]

Click or scan the QR code below to view and request a digital PDF 7-day meal plan created with a dietitian to help patients increase or maintain weight before/during cancer treatment.

Hydration should also be closely monitored as BTC and some treatments can cause side-effects such as vomiting, diarrhoea, sweating, and loss of appetite, which lead to dehydration. **Because hydration affects kidney function, this is particularly important for patients receiving cisplatin containing regimens,** to ensure they meet the required creatinine clearance thresholds for treatment. **Encouraging and emphasising the need for increased fluid intake** and recommending drinks containing salts and electrolytes where appropriate, can help to replace lost fluids and support overall wellbeing.[14,27,28]

Click or scan the QR code below to visit our website for more information on **managing hydration with low-dose cisplatin** as part of the IMFINZI (durvalumab) TOPAZ-1 regimen.

Benefits of physical activity

Physical activity can help to maintain strength and mobility in patients with BTC. Light, **supervised exercise has been shown to help counteract cancer-related muscle and weight loss typically seen in patients with BTC**, and may support patients in maintaining mobility and independence during their treatment journey.[16,29] Staying mobile can also help patients continue with everyday activities and stay socially connected.[26] **Although the window of opportunity for pre-treatment activity may be limited in BTC, even short-term or low-intensity interventions may still enhance patient** wellbeing, maintain their daily function and help them to stay on treatment for longer.

As this patient group can be more fragile due to their tumour burden, it's important to tailor exercises and reduce intensity in response to fatigue or muscle soreness.[29]

Visit our resource hub to download a patient support booklet designed to support your patients in maintaining fitness, diet, nutrition, and mental well-being throughout their treatment journey. Click or scan the QR code below to access this booklet.

Key considerations to support patient fitness and outcomes in your patients with BTC

Assessment and eligibility:

- ☑ Assess patient's ECOG Performance Status (ECOG-PS) before treatment initiation.[3,6]
- ☑ Conduct regular reassessment of ECOG-PS.[9,10]

Symptom management:

- ☑ Take a detailed clinical history to determine the nature, severity, and cause of symptoms (disease vs. treatment related).[6]
- ☑ Implement pharmacological and non-pharmacological management strategies, ensuring early involvement of palliative and supportive care teams.[6]

Biliary drainage and monitoring:

- ☑ Monitor bilirubin levels.[6]
- ☑ In case of biliary obstruction, perform ERCP as the preferred method for bile duct stenting.[6]
  - If ERCP is not feasible, consider EUS-guided biliary drainage or PTC.
- ☑ Aim for bilirubin ≤1.5 × ULN to enable eligibility for more recently available systemic treatments.[1,21]
- ☑ Use metal stents for patients with an expected survival >3 months.[2,6]

Establish a monitoring pathway post-stenting:[6]

- ☑ Schedule regular liver function tests during oncology treatment or palliative follow-up.
- ☑ Provide patients with:
  - Emergency contact numbers for reporting jaundice or related symptoms.
  - Home supply of antibiotics with clear instructions for use in suspected stent cholangitis.
- ☑ If stent blockage is suspected, arrange repeat cross-sectional imaging to confirm and guide further intervention.

Molecular profiling:[2,6,22]

- ☑ Conduct molecular profiling early (ideally before first-line therapy, and definitely before second-line therapy) to identify targetable mutations.
- ☑ When performing ERCP or PTC at diagnosis, combine with biopsy to ensure adequate tissue for pathology and molecular analysis.

Multidisciplinary team (MDT) coordination:[4]

- ☑ Hold regular MDT meetings to support accurate staging and timely decision-making including: oncologist, clinician responsible for the patient's care, surgeon, diagnostic and interventional radiologist, hepatologist, pathologist, endoscopist and gastroenterologist

Supporting metal wellbeing and caregivers:[6,25]

- ☑ Involve caregivers in discussions and refer them to support organisations (e.g., Macmillan Cancer Support, AMMF).
- ☑ Clinical Nurse Specialist (CNS) should conduct a holistic needs assessment and facilitate personalised care planning.
- ☑ Ensure early referral to psychological support (e.g., Macmillan Cancer Support, Maggie's Centres, or local cancer centres).

Nutrition and hydration:

- ☑ Perform routine nutritional screening.[16]
- ☑ For at-risk patients, refer to a registered dietitian for a full nutrition assessment and personalised nutrition care plan.[6,16]
- ☑ Monitor hydration closely, and encourage adequate fluid intake, especially in patients on cisplatin-based regimens.[14,27,28]

Physical wellbeing and rehabilitation:

- ☑ Encourage light, supervised exercise to prevent cancer-related muscle and weight loss.[29]
- ☑ Refer patients to Prehab4Cancer or similar programmes for guided exercise resources and videos.

References and abbreviations

Abbreviations:
1L, first line (treatment); AMMF, Alan Morement Memorial Fund; BSG, British Society of Gastroenterology; BTC, biliary tract cancer; BTcP, breakthrough cancer pain; CBC, complete blood count; CNS, clinical nurse specialist; CNSs, clinical nurse specialists; CUP, cancer of unknown primary; ECOG PS, Eastern Cooperative Oncology Group performance status; ENS CCA, European Network for the Study of Cholangiocarcinoma; ERCP, endoscopic retrograde cholangiopancreatography; ESMO, European Society for Medical Oncology; EUS, endoscopic ultrasound; GI, gastrointestinal; HPB, hepatobiliary pancreatic cancers; IV, intravenous; IO, immuno oncology; MASCC, Multinational Association of Supportive Care in Cancer; MDT, multidisciplinary team; NHS, National Health Service; NRS, numeric rating scale; NSAIDs, non steroidal anti inflammatory drugs; PTC, percutaneous transhepatic cholangiography; PSC, primary sclerosing cholangitis; PS, performance status; R/CINV, radiotherapy/chemotherapy induced nausea and vomiting; SC, subcutaneous; TID, ter in die (three times a day); ULN, upper limit of normal.

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