

8

IDENTIFICATION AND ASSESSMENT OF HEALTH RELATED QUALITY OF LIFE ISSUES IN PATIENTS WITH SPORADIC DESMOID-TYPE FIBROMATOSIS: A LITERATURE REVIEW AND FOCUS GROUP STUDY

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Background Sporadic desmoid-type fibromatosis (DTF) is a rare, chronic, non-metastasizing, disease of the soft tissues. It is characterised by local invasive and unpredictable growth behaviour, and a high propensity of local recurrence after surgery thereby often having a great impact on health related quality of life (HRQL). This study aims to review currently used HRQL measures and to assess HRQL issues among DTF patients.

Material and methods Approval from the Medical Ethics Committee of Erasmus MC, Rotterdam, the Netherlands, was obtained for this study (file number MEC-2017-269). A mixed methods methodology was used consisting of (1) a systematic literature review to provide an overview of measures previously used to evaluate HRQL among DTF patients; (2) focus groups to gain insight into HRQL issues experienced by DTF patients.

Results The search strategy identified thirteen articles reporting HRQL measures using a wide variety of cancer-specific HRQL tools, functional scores, symptom scales (e.g. numerical rating scale) and single-item outcomes (e.g. pain and functional impairment). No DTF specific HRQL tool was found. Qualitative analysis of three focus groups (6 males, 9 females, aged 16-75 years) showed that participants emphasised the negative impact of DTF and/or its treatment on several HRQL domains. Six themes were identified: 1) diagnosis, 2) treatment, 3) follow-up and recurrence, 4) physical domain, 5) psychological and emotional domain and 6) social domain.

Conclusion A DTF-specific HRQL tool and consensus regarding the preferred measurement tool among DTF patients is lacking. Our study indicates that HRQL of DTF patients was negatively affected in several domains. A DTF-specific HRQL measure could improve our understanding of short- and long-term effects and, ideally, can be used in both clinic and for research purposes.

Conflict of interest: No conflict of interest.

*Scientific Symposium**Breast Conserving Surgery and Locoregional Control After Neoadjuvant Chemotherapy*

9

MAGNETIC RESONANCE IMAGING FOR PREDICTION OF PATHOLOGIC RESPONSE TO NEOADJUVANT CHEMOTHERAPY IN TRIPLE-NEGATIVE BREAST CANCER

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BACKGROUND: The ability of breast MRI to predict pathologic response to neoadjuvant chemotherapy varies across biological subtypes. We sought to determine how well breast MRI findings following initial treatment on the phase III BrightNess trial correlated with pathologic response in patients with triple negative breast cancer (TNBC).

MATERIALS AND METHODS: We enrolled 634 patients with stage II-III TNBC, who received weekly paclitaxel x 12 (wP) +/-carboplatin (Cb) or Cb/veliparib (V), followed by 4 cycles of doxorubicin and cyclophosphamide, then surgery; imaging and pathologic response data were available for 519. In comparing breast MRIs performed prior to and following wP +/-Cb/V, MRI complete response (mCR) was defined as a disappearance of all target lesions and MRI partial response (mPR) as a $\geq 50\%$ percent reduction in the largest tumor diameter. Pathologic complete response (pCR) was defined as the absence of residual invasive disease in the breast and axillary nodes (ypT0/isN0), while in non-pCRs, minimal residual disease was defined as residual cancer burden class I (RCB-I), calculated per the method of Symmans et al.

RESULTS: After wP (+/- Cb/V), mCR was demonstrated in 116 patients (22%), while 166 (32%) had mPR and 237 (46%) had stable or progressive disease (SD/PD). At surgery, pCR or pCR/RCB-I was demonstrated in 78% and 89% (mCR), 57% and 75% (mPR), and 36% and 50% (SD/PD), respectively. The positive predictive value (PPV), negative predictive value, and overall accuracy of the mid-treatment MRI for eventual pCR were 78%, 56%, and 61%, respectively. Accuracy did not differ significantly between gBRCA mutation carriers and non-carriers (52% vs. 63%, p=0.10). In multivariable analyses controlling for patient and tumor characteristics, lower clinical T stage (T1 vs. T2 or T3-4) was the only factor significantly associated with both mCR (p=0.003) and pCR (p=0.007). When compared to patients with SD/PD, those with mPR or mCR were 2.34 (95% CI 1.51-3.63) and 6.12 (95% CI 3.55-10.54) fold more likely to have pCR at surgery, and 3.35 (95% CI 2.07-5.41) and 7.73 (95% CI 4.02-14.89) fold more likely to have pCR/RCB-I at surgery. MRI response during neoadjuvant therapy was significantly associated with eligibility for breast-conserving surgery following completion of treatment (93.1% for mCR vs. 81.6% for SD/PD, p<0.001).

CONCLUSIONS: Complete response on MRI performed following the initial phase of treatment on BrightNess had a PPV of 78% for demonstration of pCR after completion of neoadjuvant chemotherapy in patients with TNBC. However, a substantial proportion of patients with mPR or SD/PD also achieved pCR or RCB-I. Future studies are warranted to assess the role of imaging response during neoadjuvant chemotherapy to determine subsequent treatment and optimize surgical planning.

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Scientific Symposium New Trends in Upper GI

10

ANALYSIS OF FUNCTIONAL OUTCOMES POST GASTRECTOMY AND OESOPHAGECTOMY

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Background: Advances in gastric and oesophageal cancer management have led to improved survivorship. Factors affecting quality of life in long-term survivors are now coming to the attention of caregivers. The causes are multifactorial and include structural changes in upper gastrointestinal tract, abnormal gastrointestinal motility, altered pH, bacterial overgrowth, and insufficient bile salt or pancreatic enzyme production. The objective of this study was to analyse the extent of this problem in a gastric and oesophageal cancer population.

Materials and methods: A prospectively maintained database identified 174 patients who underwent gastrectomy for gastric cancer and 146 patients who underwent oesophagectomy for oesophageal cancer from 2006–2014. A retrospective analysis was performed to assess those referred to gastroenterology with functional symptoms. Investigations performed and subsequent results were analysed.

Results: 45/174 (26%) of patients had significant functional symptoms post gastrectomy and 33/146 (22.6%) of patients had similar problems post oesophagectomy requiring referral to gastroenterology. Concerning symptoms included weight loss, diarrhoea, nausea, and abdominal pain. 27/45 (60%) of gastrectomy patients had undergone a total gastrectomy. 32/33 (97%) of oesophagectomy patients had undergone an Ivor Lewis oesophagectomy. The most common diagnosis was small intestine bacterial overgrowth (SIBO) 40/45 (89%) gastrectomy patients were found to

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Background: The American Intergroup 0116 study (Macdonald et al; NEJM; 2001) and the British MAGIC trial (Cunningham et al; NEJM; 2006) changed clinical practice for resectable gastric cancer. It was shown that overall survival after surgery improved with postoperative chemoradiotherapy and perioperative chemotherapy, respectively. Intention-to-treat analysis of the data in the CRITICS trial (chemotherapy versus chemoradiotherapy after surgery and preoperative chemotherapy for resectable gastric cancer; Lancet Oncology; 2018) did not show a survival difference between the two treatment arms. Due to comorbidity, the aging society, treatment related toxicity and major surgery, compliance is a problem in clinical studies. A per protocol analysis was performed acknowledging the limitations of such analysis.

Material and methods: The CRITICS trial was an open label phase 3 trial in which 788 patients with stage Ib– IVa resectable gastric or oesophago-gastric adenocarcinoma were included. Patients from the Netherlands, Sweden, and Denmark were randomly assigned to perioperative chemotherapy or preoperative chemotherapy with postoperative chemoradiotherapy. For this analysis, only outcomes of patients who actually started postoperative treatment were analyzed. Since the two treatment arms are not inherently balanced in such per protocol analysis, landmark analysis (adjusting for baseline, preoperative chemotherapy, surgery and pathology variables) and Inverse Probability Weighted (IPW) analysis were used to estimate and compare overall and event-free survival.

Results: Median follow-up duration is 6.2 years.

	Randomization	Pre-operative CT	Surgery	Post-operative CT	Post-operative CRT	Completed treatment
CT	393 (100%)	334 (85%)	310 (79%)	233 (59%)		180 (46%)
CRT	395 (100%)	318 (81%)	326 (83%)		245 (62%)	197 (50%)

CT = chemotherapy; CRT = chemoradiotherapy

have SIBO, diagnosed on methane breath test or duodenal aspirate. 26/33 (79%) oesophagectomy patients were diagnosed with SIBO. Organisms isolated included E. Coli, Enterococcus, Klebsiella, Streptococcus, Clostridium and Candida. 8/45 (18%) post gastrectomy and 5/33 (15%) post oesophagectomy had bile salt malabsorption diagnosed on SeHCAT scan. 5/45 (11%) post gastrectomy and 3/33 (9%) post oesophagectomy had pancreatic insufficiency on faecal elastase testing.

Conclusions: Improved survival rates post upper gastrointestinal surgery have identified that survivors can develop functional problems months to years after surgery. The most common diagnosis is SIBO. As this is easily treated with antibiotics we would advocate early recognition and investigation of functional symptoms to avoid weight loss and distressing symptoms in this population.

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11

CHEMOTHERAPY VERSUS CHEMORADIOTHERAPY AFTER SURGERY AND PREOPERATIVE CHEMOTHERAPY FOR RESECTABLE GASTRIC CANCER: PER PROTOCOL ANALYSIS OF THE CRITICS TRIAL

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Conclusion: Actual results of the per protocol analysis as well as updated results of the intention-to-treat analysis will be presented.

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12

LAPAROSCOPY-ASSISTED VERSUS OPEN D2 DISTAL GASTRECTOMY FOR ADVANCED GASTRIC CANCER: FIVE YEAR OVERALL SURVIVAL AND MORBIDITY RESULTS FROM A RANDOMIZED PHASE II MULTICENTER CLINICAL TRIAL (COACT 1001).

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