

quality of life (QoL) in patients who had anastomotic leak after low anterior resection for rectal cancer. **METHODS:** Materials and Methods: The study group included 33 patients (6 women, 27 men; mean age 61 years) who had an anastomotic leakage after anterior resection between 1994 and 2007. Twenty-six of patients had neoadjuvant chemoradiotherapy. Leakage was major in 10 cases and as minor in 23. Median follow up was 4.8 years. The control group of 33 patients without leakage was matched for age, sex, tumor location, neoadjuvant therapy and surgical treatment. Both groups filled a questionnaire concerning bowel function, constipation, fecal incontinence and fractionated evacuation and three validated QoL questionnaires (PGWBI [Psychological Well Being Index], EORTC QLQ-C30 and QLQ-CR38). The scores for constipation (CSS) and fecal incontinence (Vaizey score) were calculated. Statistical analysis was carried out with T student test for paired data and the test on marginal homogeneity. **RESULTS:** Results: No statistically significant differences were found in the two groups for constipation. More than five evacuation/day were found in 42% patients with anastomotic leakage versus 15% of control group ( $p=0.00$ ). The comparison of Vaizey score between cases and controls was also significant: 9.4 vs 7.3 ( $p<0.03$ ) respectively. Patients with major leakage had significantly worst incontinence scores than those with minor leakage (Vaizey score 12,6 vs 8,08;  $p<0.05$ ) and than controls (Vaizey score 7,3;  $p<0.005$ ). No significant differences were found in the PGWBI and in the EORTC- QoL questionnaires, unless patients with leakage reported more micturition problems and worse sexual functioning ( $p<0.05$ ). **CONCLUSIONS:** Conclusions: In this retrospective study we found that patients with major anastomotic leakage had a worse outcome for fecal continence and evacuation; however the impact on QoL and PGWBI was not statistically significant.

#### **8/1582/Quality of life and symptom assessment in patients with myelodysplastic syndromes (MDS). An evaluation of the methodology and the quality of reported outcomes**

*Fabio Efficace, Health Outcomes Research Unit, GIMEMA, Rome, Italy, Giovanni Caocci, Dept. Hematology, Ospedale Binaghi, Cagliari, Italy, Marco Vignetti, Paola Fazi, Health Outcomes Research Unit, GIMEMA, Rome, Italy, Francesco Cottone, Health Outcomes Research Unit, GIMEMA, Rome, ., Italy, Giorgio La Nasa, Dept. Hematology, Ospedale Binaghi, Cagliari, Italy, Franco Mandelli, Health Outcome Research Unit, GIMEMA, Rome, Italy*

**AIMS:** While Patient-Reported Outcomes (PROs) are now well implemented in cancer research, there is lack of evidence in patients with hematologic malignancies. This systematic review was undertaken to evaluate traditional clinical and PROs in prospective studies of patients with MDS. **METHODS:** A systematic review was performed, broadly following the Cochrane methodology on all prospective studies having PROs as an endpoint published between 1980 and 2008. Candidate articles were identified mainly by PubMed and the Cochrane library. Two reviewers independently assessed all studies to consistently evaluate their methodological quality according to a previously developed protocol reviewer. This included a number of methodological and statistical quality criteria such as PRO missing data documentation, timing of assessment, discussion of outcomes in terms of clinical significance and PRO instrument used. Traditional clinical outcomes were also systematically reviewed. **RESULTS:** Nine prospective studies were identified, four of which evaluated PROs in a RCT setting and interestingly, all the studies were published after the year 2001. In all RCT studies PROs were used as a secondary endpoint. Six out of the nine studies included less than 100 patients thus limiting the interpretation of PROs. Methodological drawbacks were mainly identified in terms of amount of missing data over time and lack of reporting of important

details about the design of the PRO assessment. Out of the four RCTs including PROs, important evidence emerged from two studies comparing azacitidine (AZA) and decitabine versus supportive care indicating that these treatments provide beneficial effects in terms of quality of life. **CONCLUSIONS:** A number of methodological issues need to be addressed in future studies so as identified in this work. PRO evaluation significantly added in terms of understanding of overall treatment effectiveness thus providing valuable outcomes to further inform clinical decision-making.

#### **9/1588/PATIENT-REPORTED SYMPTOM BURDEN IN SUPPORTIVE AND PALLIATIVE CARE IN HEMATOLOGY. A FEASIBILITY STUDY USING THE M.D. ANDERSON SYMPTOM INVENTORY (MDASI)**

*Fabio Efficace, Health Outcomes Research Unit, GIMEMA, Rome, Italy, Claudio Cartonni, Dept. Hematology, University La Sapienza, Rome, Italy, Pasquale Niscola, Dept. Hematology, S.Eugenio Hospital, Rome, Italy, Maria Giulia Marini, Luigi Reale, Health Outcomes Unit, Fondazione ISTUD, Milan, Italy, Francesco Cottone, Health Outcomes Research Unit, GIMEMA, Rome, Italy, Andrea Tendas, Dept. Hematology, S.Eugenio Hospital, ., Italy, Maria G. Loglisci, Vincenzo Federico, Elisabetta Meloni, Dept. Hematology, University La Sapienza, Rome, Italy, Paolo De Fabritiis, Dept. Hematology, S.Eugenio Hospital, Rome, Italy, Franco Mandelli, Health Outcomes Research Unit, GIMEMA, Rome, Italy*

**AIMS:** There is paucity of patient-reported outcome (PRO) research in hematologic malignancies. Thus, this study investigates the feasibility of using a validated patient-reported symptom tool in a sample of hematologic patients. **METHODS:** Patients in supportive or palliative care treatments with various hematological malignancies are being enrolled in a prospective study comparing symptom burden in a hospital-based setting versus a home-care-based program. The MDASI consists of 19 items; the first 13 items assess symptom severity; the remaining 6 items investigate to what degree symptoms interfere with various aspects of the patient's life. Items are rated on a numeric rating scale from 0 to 10, with the higher scores indicating a higher level of symptom perception or a higher symptom interference. Symptom items were classified according to the following scores: mild (1-4), moderate (5-6) and severe (7-10). Descriptive statistics and linear regression analyses were used. **RESULTS:** Data are available for 43 patients who have so far completed the MDASI. Of these, 25 patients (58%) were in advanced stage disease. Accuracy of questionnaire completion was good, with more than 80% of patients completing all items. The percentage of missing items was low ranging between 2% (shortness of breath) and 12% (symptom interference with work activity). The symptoms most frequently reported as moderate to severe in the overall sample were fatigue (72%), dry mouth (52%), feeling sad (45%) and lack of appetite (45%). Moderate to severe pain was reported only in 37% of patients. Advanced stage patients, however, had a higher proportion of patients reporting moderate to severe fatigue (88%). **CONCLUSIONS:** While there is a lack of evidence-based data regarding symptom burden from the patients' perspective in the hematological population, this preliminary analysis suggests that fatigue is the most prevalent symptom and that measuring the patient's view on symptom burden is feasible, also in patients with advanced stage disease.

#### **10/1613/OnQoL: information system to capture quality of life data from oncology patients**

*Alexandra Oliveira, Health Sciences, University of Aveiro, Center of, Health Studies & Research, University of Coimbra, Aveiro, Portugal, Pedro L. Ferreira, Center of Health Studies & Research, University*