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OBJECTIVE: The economics of the therapy on patients with stage T1 and T2 prostate carcinoma with the alternatives Iodine 125-seed implantation in form of Rapid Strand, total prostatectomy and beam radiation is the object of this study.

METHODS AND RESULTS: The costs are calculated from the perspective of the health insurance fund, thus giving only direct costs. For the observed time period of 7 years, allowing for a discount rate of 5%, a therapy with Iodine 125-seed implantation amounted to a total of DM 3380 direct costs. The total prostatectomy resulted in a total of DM 15,298 direct costs and beam radiation was a total of DM 8058 direct costs. In calculating the output of alternative therapies, the PSA-progression free survival parameter of the patients was used to define the effectiveness. Total prostatectomy was given an effectiveness rate of 71%, for the Iodine 125-seed implantation a rate of 89% was given and for beam radiation a rate of 74.2% was given. These effectiveness rates were taken from clinical studies. The effectiveness adjusted costs then came to DM 3798 for Iodine 125-seed implantation, DM 21,547 for prostatectomy, and DM 10,859 for beam radiation treatment.

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COST OF MANAGING MUCOSITIS AND XEROSTOMIA IN HEAD AND NECK CANCER PATIENTS UNDERGOING CHEMORADIOTHERAPY (CRT) OR RADIATION (RT)

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OBJECTIVE: Treatment-related toxicities in head and neck cancer can result in high costs and treatment delay or termination. This study evaluated the practice patterns and costs associated with mucositis and xerostomia, two common toxicities in head and neck cancer.

METHODS: Information on treatment practice patterns for mucositis and severe (grade 2+) xerostomia was derived from the literature and 10 expert oncologists. Direct costs (in 1997 US dollars) were estimated for drugs, administration, laboratory procedures, healthcare visits, and hospitalization. National cost sources were used for medical resource use. The treatment time frame for acute mucositis and xerostomia episodes ranged from 3–7 weeks. Because of the long-term sequelae associated with severe xerostomia, 1-year costs were also considered in the cost estimates for this toxicity. Treatment patterns and costs were examined separately for mild (grades 1–2) and severe (grades 3–4) mucositis.

RESULTS: The treatment course for severe xerostomia included oral saline rinses, pilocarpine, dental and nutri-

tionist visits, and fluoride gel. The cost of these treatments was \$2144 per episode (including 1-year costs); 75% was attributable to dental care. Treatment for grades 1–2 mucositis included prescription analgesics, oral rinses, PEG tube placement, nutritional supplements, antifungals, and physician/nurse visits. The average cost was \$913. A grade 3–4 mucositis episode cost \$4543; 72% related to nutritional complications, including hospitalization.

CONCLUSION: The results of this study indicate that the cost of managing mucositis and xerostomia is substantial. The use of prophylactic cytoprotective agents should be considered to protect the oral mucosa from CRT and RT damage, and to minimize resource use.

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PATIENT BENEFIT QUESTIONNAIRE (PBQ) FOR XEROSTOMIA: DEVELOPMENT AND VALIDATION REPORT

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OBJECTIVE: Determine the validity and reliability of the Patient Benefit Questionnaire (PBQ), an 8-item patient self-report instrument designed to assess xerostomia-related outcomes in patients (such as radiation treated head and neck cancer patients) with reduced salivary flow.

METHODS: The conceptual model, reliability, validity, responsiveness, and interpretability were evaluated using the instrument-review criteria developed by the Scientific Advisory Committee (SAC) of the Medical Outcomes Trust. Data were collected in a 1-year clinical trial comparing amifostine to control in 315 head and neck cancer patients undergoing radiation therapy.

RESULTS: Validity of the PBQ was demonstrated by factor analytic confirmation of the conceptual model. Internal consistency (Cronbach's alpha) of 0.78 and test-retest of 0.87 for the PBQ scale exceeded minimum SAC standard (0.7) for scale reliability. The PBQ average score showed acceptable ceiling and floor effects as well as adequate variability. Construct validity was demonstrated by correlation of the PBQ score in the expected direction with clinician assessments of xerostomia, mucositis, and weight change. Responsiveness to change and interpretability of PBQ scores were demonstrated by approximately a 1-point change in the PBQ score associated, on average, with a 1-grade change in a clinician-rated xerostomia toxicity score.

CONCLUSIONS: The 8-item PBQ was found to be a reliable, valid and responsive measure to assess xerostomia outcomes in head and neck cancer patients undergoing radiotherapy. The PBQ scores were found to be relevant measures of clinical benefit and interpretable due to the strong link to xerostomia toxicity scores.