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Abstract selection

Comparative outdoor study of the efficacy, onset and duration of action, and safety of cetirizine, loratadine, and placebo for seasonal allergic rhinitis. Meltzer, E. O., Weiler, J. M., Widlitz, M. D. Allergy and Asthma Medical Group and Research Center, San Diego, CA 92123, USA. *Journal of Allergy and Clinical Immunology* (1996) February, Vol 97 (2), pp 617–26.
BACKGROUND: Cetirizine, a new once-daily highly specific H1-antagonist, has been shown in conventional studies to be efficacious in the treatment of seasonal and perennial allergic rhinitis and chronic idiopathic urticaria. OBJECTIVE: The efficacy, duration and onset of action, and safety of cetirizine, 10 mg once daily, was compared with that of loratadine, 10 mg once daily, and placebo in a field study of patients with seasonal allergic rhinitis. METHODS: This was a randomized, double-blind, parallel, double-dummy study conducted over 2 days in spring allergy season at outdoor parks in San Diego and Iowa City. Study medication was administered at 10.00 am on both days. After screening, eligible patients completed rhinitis symptom diaries in the park hourly from 7.30 to 9.30 am (baseline); at 10.30 am and hourly from 11.00 am to 4.00 pm (period I); at 6.00, 8.00, and 10.00 pm at home (period II); and the next day in the park hourly from 8.00 to 10.00 am (period III), and from 11.00 am to 4.00 pm (period IV). Major and total symptom complex scores, global efficacy and overall satisfaction, and adverse events were assessed. RESULTS: Of the 279 patients (140 men and 139 women; mean age, 29 years) randomized to treatment, 278 were included in the efficacy analysis. Cetirizine produced significantly greater mean reductions than loratadine or placebo in major symptom complex severity scores at all periods ($p <$ or $= 0.05$), except period I for placebo. Cetirizine also produced mean reductions in total symptom complex severity scores that were superior to loratadine at every evaluation period ($p<0.05$) and were statistically different from placebo at period II ($p<0.01$). A rapid onset of action was observed with cetirizine, as was a better response pattern in the patient global assessment of efficacy compared with loratadine. Study medications were well tolerated; no patient stopped treatment because of side effects. The incidence of somnolence with cetirizine was 13 per cent versus 2 per cent with placebo ($p<0.05$); headache occurred more frequently with loratadine (23 per cent) than with cetirizine (11 per cent, $p = 0.03$). CONCLUSIONS: Cetirizine relieved rhinitis symptoms more effectively and quickly than loratadine and placebo in this field study of seasonal allergic rhinitis. Both active agents were generally well tolerated. Author.

Intranasal fluticasone propionate versus loratadine in the treatment of adolescent patients with seasonal allergic rhinitis. Jordana, G., Dolovich, J., Briscoe, M. P., Day, J. H., Drouin, M. A., Gold, M., Robson, R., Stepner, N., Yang, W. Department of Pediatrics, McMaster University, Hamilton, Ontario, Canada. *Journal of Allergy and Clinical Immunology* (1996) February, Vol 97 (2), pp 588–95.
Fluticasone propionate (FP) is a topical corticosteroid with minimal systemic activity. We examined safety and compared the efficacy of FP aqueous nasal spray, 200 micrograms every day with loratadine tablets, 10 mg by mouth every day in 240 adolescents with ragweed pollen-induced seasonal allergic rhinitis for 4 weeks in a randomized, double-blind, parallel-group study. Nasal and eye symptoms were recorded daily on a 4-point (0 to 3) scale. A higher percentage of symptom-free days was observed for nasal blockage on waking during treatment with FP ($p<0.0001$). Significant results were also obtained for all other nasal symptoms when analysed for both symptom-free days and symptom scores. No differences were found for eye irritation symptoms ($p = 0.14$). Morning and evening nasal peak inspiratory flow (PIF) was recorded daily by 57 subjects. FP treatment was associated with significantly higher PIF values than loratadine both morning ($p = 0.0051$) and evening ($p = 0.0036$). A greater improvement over 4 weeks was observed for PIF morning values in the FP group ($p = 0.008$) but not for evening values ($p = 0.358$). Statistically significant correlations were found for nasal blockage and PIF in the morning ($r = -0.54$, $p = 0.0001$) and in the evening ($r = -0.46$, $p = 0.008$). Author.

Increased levels of exhaled nitric oxide during nasal and oral breathing in subjects with seasonal rhinitis. Martin, U., Bryden, K., Devoy, M., Howarth, P. Clinical Pharmacology Group, Southampton General Hospital, England. *Journal of Allergy and Clinical Immunology* (1996) March, Vol 97 (3), pp 768–72.
BACKGROUND: Allergic rhinitis is associated with nasal mucosal inflammation. Exhaled nitric oxide may be a useful marker of inflammation and has recently been shown to be increased in patients with asthma. OBJECTIVE: The purpose of this study was to determine whether exhaled levels of nitric oxide are increased with nasal breathing in patients with seasonal allergic rhinitis compared with nonatopic individuals and whether there is an increase with oral breathing consistent with lower respiratory inflammation in the absence of clinical asthma. METHODS: Nitric oxide levels in exhaled air were measured by chemiluminescence in 18 nonatopic volunteers and 32 patients with seasonal rhinitis. Measurements were made with both nasal and oral exhalation and orally after 10 seconds and 60 seconds of breath-holding. The detection limit was 1 part per billion (ppb). RESULTS: In control subjects nasal levels of nitric oxide in exhaled air (mean ± SD, 24.7 ± 9.2 ppb) were higher than those after oral exhalation (11.1 ± 2.5 ppb, $p<0.0001$). Breath-holding significantly increased levels of nitric oxide in exhaled air in a time-dependent manner. Levels of exhaled nitric oxide were significantly higher for all measurements in patients with seasonal rhinitis, with levels without breath-holding of 35.4 ± 11.3 ppb ($p<0.001$) in nasally exhaled air and 16.3 ± 5.9 ppb ($p<0.001$) in orally exhaled air. Nasal levels were significantly higher than oral levels in subjects with rhinitis ($p<0.0001$). CONCLUSIONS: The results indicate that exhaled nitric oxide may be a useful marker for nasal inflammation in patients with seasonal rhinitis and suggest that generalized airway inflammation may be present, even without clinical asthma, in such patients. Author.

Sensory information from the upper airway: role in the control of breathing. Sant-Ambrogio, G., Tsubone, H., Sant-Ambrogio, F. B. Department of Physiology and Biophysics, University of Texas Medical Branch, Galveston 77555-0641, USA. *Respiratory Physiology* (1995) October, Vol 102 (1), pp 1–16.
The functional integrity of extrathoracic airways critically depends on the proper orchestration of the activities of a set of patency-maintaining muscles. Recruitment and control of these muscles is regulated by a laryngeal and trigeminal affects that originate from pressure sensing endings. These sensors are particularly numerous among laryngeal receptors and, indeed, they constitute the main element in the respiration-modulated activity of the superior laryngeal nerve. Considering that the most compliant region of the upper airway, and thus more vulnerable to inspiratory collapse, lies cranially to the larynx, the laryngeal pressure-sensing endings seem to be ideally located for detecting collapsing forces and initiating reflex mechanisms for the preservation of patency. This process operates by activating upper airway dilating muscles and by decreasing inspiratory drive: both actions limit the effect of the collapsing forces. Cold reception is differently represented in various mammalian species within nasal and laryngeal segments.

Cooling of the upper airway has an inhibitory influence on breathing, especially in newborns, and a depressive effect on upper airway dilating muscles. The latter response is presumably mediated through the inhibitory effect of cooling on laryngeal pressure endings. These responses could be harmful during occlusive episodes. Powerful defensive responses with distinct characteristics can be elicited through the simulation of laryngeal and nasal irritant type receptors. Sneezing is elicited through the stimulation of trigeminal afferents, cough through the stimulation of laryngeal vagal endings. Changes in osmolality and ionic composition of the mucosal surface liquid can lead to conspicuous alterations in receptor activity and related reflexes. Author.

Orthodontics and temporomandibular joint internal derangement. Katzberg, R. W., Westesson, P. L., Tallents, R. H., Drake, C. M. Department of Radiology, University of California Davis Medical Center, Sacramento, USA. *American Journal of Orthodontics and Dento-Facial Orthopaedics* (1996) May, Vol 109 (5), pp 515–20.
The purpose of this investigation is to compare the prevalence of internal derangement of the temporomandibular joints (TMJ) in asymptomatic volunteers versus symptomatic subjects using magnetic resonance imaging (MRI), with a detailed comparison to clinical signs and symptoms and with attention to a prior history of orthodontic treatment. Bilateral MRI scans were obtained of the TMJs in 76 asymptomatic volunteers and 102 symptomatic patients. A comparison was made to the clinical signs and symptoms, a history of orthodontic treatment, and to the MR findings. The MRI scans were reviewed using established criteria for disc displacement and the reviewers were blinded as to the clinical information. Our results show a prevalence of disc displacement in 25 of 76 (33 per cent) volunteers and 79 of 102 (77 per cent) patients with a statistically significant difference ($p<0.001$). No statistical link was noted between a history of prior orthodontic treatment and internal derangement of the TMJ. Author.

Inflammatory myofibroblastic tumor of the larynx. A clinicopathologic study of eight cases simulating a malignant spindle cell neoplasm. Wenig, B. M., Devaney, K., Bisceglia, M. Department of Otolaryngic and Endocrine Pathology, Armed Forces Institute of Pathology, Washington, District of Columbia, USA. *Cancer* (1995) 1 December, Vol 76 (11), pp 2217–29.
BACKGROUND: Inflammatory myofibroblastic tumours of the larynx are uncommon lesions that easily may be misinterpreted as malignant epithelial or mesenchymal spindle cell neoplasms. METHODS: Eight cases of laryngeal inflammatory myofibroblastic tumours were identified from the files of the Otolaryngic Tumor Registry—Armed Forces Institute of Pathology. Clinical records and follow-up were available in all cases. The light microscopic features (haematoxylin and eosin and special histochemical stains) were evaluated in all cases; immunohistochemical analysis was performed in the seven cases with available paraffin blocks; in four cases ultrastructural analysis was done. RESULTS: The patients included five males and three females ranging in age from 19–69 years (median, 59 years). Presenting symptoms included hoarseness, dysphonia, or rapidly progressive stridor with the duration of symptoms ranging from 10 days to four months. The most common site of involvement was the true vocal cord. The lesions appeared as polypoid or pedunculated masses. Histologically, the cellularity of the lesions varied, consisting of spindle-shaped to stellate cells with no consistently discernible growth pattern, in a fibromyxoid stroma that included a mixed inflammatory cell infiltrate. Features suggesting a malignant cellular infiltrate were not present. The spindle-shaped cells had consistent immunoreactivity with vimentin, muscle specific actin, and smooth muscle actin. Ultrastructurally, intracytoplasmic microfilaments were identified. In seven of the patients, conservative but complete excision of the lesion was curative; these patients have been free of disease over periods ranging from 12 to 36 months. In one patient, the lesion recurred twice over a two-year period and ultimately required a total laryngectomy. This patient died of unrelated causes. CONCLUSIONS: Inflammatory myofibroblastic tumours of the larynx are unusual benign proliferative lesions. Conservative surgical management is advocated and is curative. Recurrence is rare, but metastases disease or death attributable to these lesions is not. Author.

Aggressive psammomatoid ossifying fibromas of the sinonasal region: a clinicopathologic study of a distinct group of fibro-osseous lesions. Wenig, B. M., Vinh, T. N., Smirniotopoulos, J. G., Fowler, C. B., Houston, G. D., Heffner, D. K. Department of Otolaryngic and Endocrine Pathology, Armed Forces Institute of Pathology, Washington, DC 20306-6000, USA. *Cancer* (1995) 1 October, Vol 76 (7), pp 1155–65.
BACKGROUND: Psammomatoid ossifying fibromas represent a unique subset of fibro-osseous lesions of the sinonasal tract. They have distinctive histomorphologic features and a tendency toward locally aggressive behaviour, including invasion and destruction of adjacent anatomic structures. METHODS: Seven cases of psammomatoid ossifying fibromas of the sinonasal tract were identified in the files of the Otolaryngic Tumor Registry at the Armed Forces Institute of Pathology. Medical records, including the clinical history, location of the lesions, radiographs, treatment, and follow-up were reviewed in each case. Follow-up information was available in all of the cases. RESULTS: Four of the patients were male and three were female. The patients' ages ranged from 5 to 54 years (median age, 33 years). Symptoms included facial swelling, nasal obstruction, pain, sinusitis, headache, and proptosis. Radiographic studies confirmed the presence of an osseous and/or soft tissue mass varying in appearance from well demarcated without invasion or erosion to invasive with bone erosion and intracranial extension. Sites of involvement included the nasal cavity and all paranasal sinuses, particularly the ethmoid and maxillary sinuses. Often, more than one sinus was involved and extension of disease included involvement of the orbit, nasopharynx, palate, and anterior cranial fossa. The histologic appearance was characterized by the presence of small mineralized (psammomatoid) bodies admixed with a cellular stroma with a variable amount of myxomatous material and scattered giant cells. Confusion with other osseous and soft tissue tumours may occur resulting in too limited or too aggressive management. En bloc surgical excision is the treatment of choice and may prove curative. Aggressive behaviour with recurrence(s) or invasion into adjacent structures occurred. At the time of this writing, the patients are alive over follow-up periods ranging from six months to seven years. CONCLUSIONS: Gnathic and midfacial fibro-osseous proliferations are a diverse group of lesions. A subset of these fibro-osseous lesions with predilection for the sinonasal tract were identified. These lesions are characterized by their distinctive histology, including psammomatoid ossicles and their locally aggressive growth. Complete surgical removal is the treatment of choice. Author.

Cutaneous plexiform schwannoma associated with neurofibromatosis type 2. Val-Bernal, J. F., Figols, J., Vazquez-Barquero, A. Department of Anatomical Pathology, Marques de Valdecilla University Hospital, Medical Faculty, University of Cantabria, Santander, Spain. *Cancer* (1995) 1 October, Vol 76 (7), pp 1181–6.
BACKGROUND: Plexiform schwannoma (PS) is a rare benign tumour of the nerve sheath that can be located either in the deep soft tissues or in the dermis or subcutis. The tumour predominantly affects young adults and occurs most commonly as a slowly growing asymptomatic solitary nodule in the head and neck region, trunk, and upper extremities. METHODS: A cutaneous PS located in the preauricular region of a 19-year-old white female is reported. The patient exhibited six 'café-au-lait' spots in the trunk and the extremities. Magnetic resonance imaging examination showed bilateral tumours in both acoustic nerves (considered schwannomas) and also masses in the right major sphenoidal wing, falx, and T2–T3 level of rachis and a solid and cystic tumour in the low medulla oblongata. Tumours of the preauricular region, medulla oblongata, spinal cord at level T2–T3, and major sphenoidal wing area were surgically removed. The tumours were studied by immunohistochemistry and diagnosed as PS, pilocytic astrocytoma, and meningiomas, respectively. RESULTS: Seventy-eight cases of PS have been reported in the literature: eight (10.2 per cent) have been associated with clinical schwannomatosis, six (7.7 per cent) with multiple cutaneous schwannomas syndrome, and only three (3.8 per cent) with neurofibromatosis type 1 (NF-1). CONCLUSIONS: In this report, to the authors' knowledge, for the first time PS is described associated with neurofibromatosis type 2. The tumour does not appear to have significant association with NF-1. Plexiform schwannoma should be recognized because it may be misdiagnosed as plexiform neurofibroma or other plexiform malignant tumours. Differentiation from plexiform neurofibroma is important, because the latter is virtually

pathognomonic of neurofibromatosis type 1 and has a propensity for malignant transformation. Author.

Soft tissue sarcoma of the head and neck in children and adolescents. Lyos, A. T., Goepfert, H., Luna, M. A., Jaffe, N., Malpica, A. Department of Head and Neck Surgery, University of Texas M. D. Anderson Cancer Center, Houston 77030, USA. *Cancer* (1996) 1 January, Vol 77 (1), pp 193–200.
BACKGROUND: The experience of one institution in treating soft tissue sarcomas of the head and neck in a paediatric population is presented. METHODS: Case materials of 134 patients younger than 20 years who were referred to the University of Texas M. D. Anderson Cancer Center between 1970 and 1989 for treatment of sarcoma of the head and neck were retrospectively reviewed. Patients with rhabdomyosarcoma underwent multimodality treatment consisting of surgery, irradiation, and chemotherapy. Wide resection was the treatment used for patients with non-rhabdomyosarcomatous soft tissue sarcomas (NRSTS). Adjuvant chemotherapy and irradiation were used to treat high grade neoplasms and residual disease. The clinical response to therapy was measured in terms of the disease-specific survival rate. RESULTS: Seventy-nine of the 134 patients presented with untreated or biopsy-proven disease. Fifty-six had rhabdomyosarcoma and 23 had NRSTS. At two and five years, the disease-specific survival rates for patients with rhabdomyosarcoma were 74 per cent and 63 per cent, respectively, and patients with NRSTS had 80 per cent and 75 per cent disease-specific survival rates at two and five years, respectively. CONCLUSIONS: Rhabdomyosarcoma of the head and neck in children is effectively treated with multimodality therapy. Prognostic indicators for rhabdomyosarcoma include completeness of tumour resection and the development of recurrent disease. Aggressive surgical resection is the treatment of choice for patients with NRSTS. Prognostic indicators for NRSTS include completeness of tumour resection and the development of recurrent disease. Author.

The Performance Status Scale for Head and Neck Cancer Patients and the Functional Assessment of Cancer Therapy–Head and Neck Scale. A study of utility and validity. List, M. A., D-Antonio, L. L., Cella, D. F., Siston, A., Mumby, P., Haraf, D., Vokes, E. University of Chicago Cancer Research Center, Illinois 60637, USA. *Cancer* (1996) 1 June, Vol 77 (11), pp 2294–301.
BACKGROUND: The goal of this investigation was to examine the relationship between, and application of, two disease specific quality of life (QL) measures currently being employed for head and neck cancer patients: the Functional Assessment of Cancer Therapy–Head and Neck Scale (FACT–H&N) and the Performance Status Scale for Head and Neck Cancer Patients (PSS–HN). METHODS: The FACT–H&N and PSS–HN were administered to 151 head and neck cancer patients with a range of disease sites, treatment status (on vs. off treatment), and treatment modalities (surgery, radiation, and chemotherapy). RESULTS: FACT–H&N subscale and total scores and PSS–HN subscale scores proved sensitive to patients groups (showed significant and clinically meaningful differences) on the basis of treatment status (on vs. off treatment) and global performance status (Karnofsky scores). The pattern of correlations between FACT–H&N and PSS–HN subscales supported the scales' construct (convergent vs. divergent) validity. The strongest and most significant associations were observed between PSS–HN Normalcy of Diet and Eating in Public, and the head and neck subscale (HNS) of FACT–H&N, both of which were designed to measure the unique problems of head and neck cancer patients. More modest associations were observed between subscales measuring physical and functional areas of performance, social functioning, and emotional well-being. CONCLUSIONS: The FACT–HNS was found to be reliable and valid when applied to head and neck cancer patients. It clearly adds information to that collected by the parent (core) instrument. The PSS–HN also provides unique information, independent of that provided by the Karnofsky or the FACT–H&N. This study supported the multidimensional nature of QL for head and neck cancer patients, and thus the importance of assessing disease specific concerns in addition to general health status when assessing functional and QL outcome. Author.

The efficacy of nebulized budesonide in dexamethasone-treated outpatients with croup. Klassen, T. P., Watters, L. K., Feldman, M. E., Sutcliffe, T., Rowe, P. C. Department of Pediatrics, University of Ottawa, Ontario, Canada. *Pediatrics* (1996) April, Vol 97 (4), pp 463–6.
OBJECTIVE: To determine the added clinical benefit of nebulized budesonide in children with mild to moderate croup treated with 0.6 mg/kg oral dexamethasone. DESIGN: Randomized, double-blind, placebo-controlled trial. SETTING: Emergency department of a tertiary-care paediatric hospital with 47,000 visits per year. PARTICIPANTS: Children three months to five years of age with a syndrome consisting of hoarseness, inspiratory stridor, and barking cough and a croup score of three or greater after at least 15 minutes of mist therapy. Patients were excluded from the study if they had diagnoses of epiglottitis, chronic upper or lower airway disease (not including asthma), or severe croup or had received corticosteroids within the preceding two weeks. INTERVENTION: All patients received 0.6 mg/kg oral dexamethasone and were randomly assigned to receive 4 mL (2 mg) of budesonide solution (n = 25) or 4 mL of 0.9 per cent saline solution (n = 25) by updraft nebulizer with a continuous flow of oxygen at 5 to 6 L/min. MAIN OUTCOME MEASURES: The primary outcome measure was the proportion of patients in each group who had clinically important changes (two points) in the croup score during the four hours after treatment. RESULTS: Eighty-four per cent (n = 21) of the patients who received budesonide had clinically important responses, compared with 56 per cent (n = 14) in the placebo group. The number of patients who would need to be treated with nebulized budesonide for one patient to have a clinically important response is four patients. CONCLUSIONS: Despite receiving simultaneous oral dexamethasone, paediatric outpatients with mild to moderate croup have added, clinically important improvement in respiratory symptoms after treatment with budesonide. Author.