ABSTRACTS

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CHARACTERISTICS OF PATIENTS RECEIVING PHARMACEUTICAL SAMPLES AND ASSOCIATION BETWEEN SAMPLE RECEIPT AND OUT-OF-POCKET PRESCRIPTION COSTS. G. Alexander, J. Zhang, A. Basu, University of Chicago, Chicago, IL.

Background: Pharmaceutical samples are widely used for promotion and marketing, yet little is known about who receives samples or how their use is associated with patient's prescription costs. **Objective:** To examine the characteristics of patients receiving samples and to describe the association between sample receipt and prescription costs. **Design, Setting, and Participants:** We divided the 2002–2003 Medical Expenditure Panel Survey, a nationally representative, panel-design longitudinal study, into baseline and analysis periods. We conducted logistic and generalized linear regression analysis of 5,709 individuals in the analysis period who did not receive any samples during the baseline period. **Measurements:** (1) Sample receipt and (2) prescription expenditures **Results:** A total of 781 (14%) individuals received at least one sample during the analysis period. On multivariate analyses, sample receipt was greater among those who were younger and those not on Medicaid. In generalized linear regressions controlling for demographic characteristics and health care use, the 180-day out-of-pocket prescription expenditures were $178 (standard error [SE] $3.9) for those never receiving samples. Among those receiving samples, the corresponding out-of-pocket expenditures were $166 (SE $8.9) for periods before sample receipt, $244 (SE $9.2) for periods during sample receipt, and $212 (SE 12.4) for periods following sample receipt. Results were similar when total prescription costs were examined. **Limitations:** Sample use was based on self-report, the analysis period was limited to 12 months, and the associations observed may not be causal. **Conclusions:** Individuals receiving samples have higher prescription expenditures than their counterparts. This finding, which may be from sample-induced demand for prescriptions, as well as greater illness among sample recipients, suggest that sample recipients may be disproportionately burdened by prescription costs even after sample receipt.

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EROSIVE ARTHRITIS IN SYSTEMIC SCLEROSIS. S. Arami, M. Gambhir, K.K. Chouhan, W. Swedler, University of Illinois at Chicago, Chicago, IL.

Introduction: Joint involvement in systemic sclerosis (SSc) was first described by Forget in 1847.[1] Rodnan studied a series of 150 cases with SSc and noted that 41% had arthritis and arthralgia within 1 year of onset of Raynaud's phenomenon (RP) and/or cutaneous signs.[2] Some of the x-ray findings of SSc include soft tissue atrophy, loss of joint space, osteoporosis, calcinosis, and acro-osteolysis. Although rare, erosive arthritis has been noted in the past. We observed three patients with erosive joint manifestations involving different joints in SSc. **Case Reports:** *Case 1:* A 47-year-old female with a history of sclerodactyly, RP, polyarthralgias, dysphagia, GERD, and pulmonary hypertension. Physical examination (PE) was consistent with (c/w) diffuse sclerosis, calcinosis over the elbows, hyperpigmentation, digital ulcers, tapering of the digits, and diminished range of motion of the wrists and elbows. Laboratory testing (LT) revealed a positive anti-SSA and anti-Scl 70 antibodies, weakly positive rheumatoid factor (RF), and negative RNP/SM and ANA antibodies. Radiographs showed erosions of IP, MCPs, MTPs, and radioulnar joint, along with the acro-osteolysis of the hand and calcinosis of the right thumb and right third digit. *Case 2:* A 31-year-old female with a history of RP, dysphagia, GERD, sclerosis, and polyarthralgias. PE was c/w sclerodactyly, flexion contractures (FC) of the PIPs and DIPs, diffuse sclerosis, and digital ulcers. LT revealed positive anti-Scl-70 antibody and negative RF, ANA, and RNP/SM antibodies. MRI of the left knee showed diffuse synovial proliferation, tendinosis, and periarticular osseous erosions of the tibia. Hand radiograph was c/w narrowing of the carpal bones. *Case 3:* A 48-year-old female with a history of RP, ILD, polyarthralgia, and polyarthritis. PE was c/w sclerodactyly and telescoping of the digits, FC and calcinosis of elbows, and FC of the knees and wrists. LT revealed positive anti-Scl-70 antibody and negative RF and RNP/SM antibody. X-ray findings showed erosions of the distal end of the humerus and tapering of the ulna and extensive calcinosis of the wrists, elbows, and knees. **Discussion:** Ninety percent of the patients with SSc present with articular findings. Acro-osteolysis is the most common x-ray finding in SSc. Rabinowitz et al reviewed the x-ray findings of 24 patients with SSc; bone erosions were seen in 13 patients.[3] In the above cases, erosive arthritis involved the small joints of the hand, wrist, elbows, and knees, simulating rheumatoid arthritis (RA). Only one of three patients had a weakly positive RF, but none had a history or physical examination findings suggestive of RA. Two patients had erosive changes involving the IP, MCPs, and distal radioulnar and carpal bones. One patient had minimum erosions in the hand and extensive erosions of the knees on MRI. We propose that these patients represent a unique population of SSc patients in that they have erosive changes quite distinctive of SSc.

References

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2. Rodnan GP. The nature of joint involvement in progressive systemic sclerosis (diffuse scleroderma). Ann Intern Med 1962;56:422.
3. Rabowitz JG, Twersky J, Guttadauria M. Similar bone manifestations of scleroderma and rheumatoid arthritis. Radiology 1974;121:35–44.

Summary of the Cases

Case No.	Age (yr), Sex	Clinical Diagnosis	Lab Analysis		Radiographic Analysis	
			RF	ANA	Articular Erosions	Others
1	47, F	SSc	+VE	−VE	IP, MCP, MTP, radioulnar joint	Soft tissue calcification, acro-osteolysis of hand
2	31, F	SSc	−VE	−VE	Proximal tibia	Narrowing of radiocarpal joint
3	48, F	SSc	−VE	−VE	Distal humerus and ulna	Soft tissue calcification of wrist, elbow, and knee

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RATE OF UNDIAGNOSED COGNITIVE IMPAIRMENT IN COMMUNITY SETTINGS: IS THERE A NEED FOR SCREENING? D. Baker, N. Yasui, N.J. Lane, T.L. Ohrt, S. Asthana, CE Gleason, University of Wisconsin, Madison, WI.

The Midwest Initiative for Dementia Screening (MINDS) Project, funded by Extendicare Foundation, proposed to improve early detection of previously undiagnosed cognitive impairment in community-dwelling individuals through memory screenings and educational lectures. Our goals were first to assess the rate of undiagnosed cognitive impairment and to provide appropriate referral information for individuals in need of further evaluation. The community screenings were not intended to provide diagnoses but rather to identify individuals in need of a clinical evaluation. Still, participants with limited access to neuropsychological services were provided with a summary of screening data sufficiently extensive to serve the purpose of a clinical evaluation. The data could be used by a primary care provider (PCP) within the context of a comprehensive clinical diagnostic evaluation. We provided memory screenings for 260 individuals, screened at one of eight locations around southern Wisconsin. Of those screened, 203 (78%) were women with a mean age of 77 years. Male participants had a mean age of 83 years. Of the 260 individuals screened, 129 (50%) showed no evidence of cognitive impairment, scoring at or above the normal range on cognitive tests. Testing also confirmed a previous diagnosis of a memory disorder for 24 individuals (9%). The remaining 107 (41%) individuals demonstrated varying degrees of cognitive impairment on testing, presumably undetected. Performance on screening tests was considered with medical history and current medications. Based on the totality of information gathered, we suspected that 35 individuals demonstrated cognitive impairments in multiple cognitive domains and that the deficits were not adequately explained by other medical conditions or concurrent treatments. These individuals (33% of the 107) subsequently received a recommendation for a full diagnostic workup to determine if their screening performances were the result of a neurodegenerative disease such as Alzheimer's dementia. The 30 individuals (28% of the 107) demonstrating focal memory impairment on screening measures, not attributed to other medical conditions or treatments, were referred for further evaluation to assess for a mild cognitive impairment. The remaining 42 (39%) were encouraged to discuss issues such as medications, depression, and anxiety with their PCP and monitor their condition. We also compared the Mini Mental Status Exam (MMSE) scores of all participants with the results of their full memory screening performance. A score of 24 or lower on the MMSE was considered impaired. Of the 260 participants, 21 (8%) scored in the impaired range on the MMSE. Twelve of those participants had their memory disorder confirmed by our testing, leaving 9 of the remaining 248 participants (4%) scoring in the impaired range. PCPs often rely on a MMSE to quickly gauge the cognitive functioning of patients and alert them to impairment. However, our findings indicate that only 8 individuals (7%) of the 107 suspected here to have cognitive impairment demonstrated impairment on the MMSE. In other words, the cognitive decline in 93% of the participants who demonstrated impairment on our testing would have gone unnoticed if the MMSE was relied on as the sole screening method. The MINDS project revealed that older adults residing in the community are indeed interested in participating in memory screenings. Consistent with previous reports, nearly half demonstrated some level of cognitive impairment, warranting follow-up evaluation. Furthermore, data gathered in similar screenings could be used by PCP in communities where there is limited access to neuropsychological services, reducing reliance on the MMSE as the only tool to assess cognition.

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"WAS IT WORTH IT?" A PILOT STUDY OF ADVANCED CANCER PATIENTS' RETROSPECTIVE PERCEPTIONS OF BENEFIT FROM PHASE I TRIAL PARTICIPATION. J.Y. Bruce, F.J. Hlubocky, C.K. Daugherty, University of Chicago Medical Center, Chicago, IL.

Background: The scientific aims of phase I oncology trials are to evaluate the safety and tolerability of new therapeutic agents. Subjects who enrol in phase I oncology trials generally are advanced cancer patients (ACPs) for whom standard treatments have either failed, have low expectation of benefit, or do not exist. Although all ACPs undergo an informed consent process prior to trial participation, there is evidence that ACPs may not appreciate the primary aims of a phase I trial and also have unrealistic expectations of therapeutic benefit. However, these perceptions of benefit have not been well described. A pilot study was performed to examine and evaluate these perceptions from ACPs who participated in phase I oncology trials. **Methods:** In this pilot study, patients who were enrolled in phase I trials were interviewed retrospectively regarding their perceptions of benefit after withdrawal from a phase I trial. To date, a total of nine ACPs have been interviewed: median age 72 years (range 59–82 years); 55% male; 77% Caucasian. Their qualitative responses were recorded and analyzed for content and themes. The interview included open-ended questions assessing patient experiences with the trial, including reasons for enrolment, impressions of improvement in quality of life, costs incurred, and other benefits. **Results:** Stated reasons for enrolment include hope, prior treatment failure, altruism, and family influence. Described patient perceptions of anticipated trial benefit included stabilization of disease and close monitoring of their disease. Unexpected costs incurred during trial participation were time spent during clinic visits, financial costs with transportation, time taken off work by family members to support trial participation, time spent away from the family, and additional procedures associated with the trial. Issues of quality of life during the trial revolved around side effects from the investigational agent. Many interviewed patients (44%) describe their current quality of life off the trial as being improved compared with quality of life during phase I trial participation. The majority of interviewed patients (67%) acknowledged that the trial did not impact their overall survival. **Conclusions:** Our data suggest that ACPs had perceptions of significant therapeutic benefit prior to enrolment, including stabilization of disease, close monitoring of their disease, and an improvement in overall survival and quality of life. There would appear to be significant and unanticipated out-of-pocket expenses incurred by subjects and their families as a result of phase I trial enrolment. Further research is needed to examine the multiple factors, such as side effects, unexpected costs, and lack of improved survival, that contribute to these individuals' perceptions of benefit from trial participation.