1407 Scientific Abstracts

and histological studies have revealed that the accelerated bone turnover is associated with an increased blood flow and hypervascularity, suggesting a role of high-resolution sonography with power-Doppler (PD) and color- Doppler (CD) in Paget's disease. Our preliminary data demonstrated that this technique shows not only the alterations of the pagetic bone profile, but also the hypervascularization of the osteoperiosteal-layer, both at the diagnosis and during follow-up.

Objectives: To validate the PD technique as a useful tool not only for the diagnosis of Paget's disease of bone but also for the evaluation of the disease activity and for the monitoring of the therapeutic response.

Methods: Forty-three consecutive patients affected by Paget's disease of bone and treated with neridronate were followed up over the last ten years. Patients were classified in eight clinical patterns defined by the presence of bone alkaline phosphatase elevation over the normal range (BAP+), bone pagetic pain as visual analogue scale ≥30 (VAS+) and PD alterations of osteoperiosteal vascularization (PD+). Data were analyzed by Fisher exact test (two tails) to assess the associations between BAP+, VAS+ and PD+ at different times during follow up: before the start of the therapy, after the first, the second and the third neridronate cycle of therapy, and at the end of all cycles.

Results: At any time BAP+ and VAS+ were not associated. A trend of association between VAS+ and PD+ could be observed only after the first neridronate cycle. In contrast, the association between BAP+ and PD+ was statistically significant before the therapy, at the end of all cycles of therapy and after the second one, but not after the first one.

Table 1. Associations between BAP elevation over the normal range, VAS and PD alterations of osteoperiosteal vascularization, p<0.05

|                                  | BAP+/VAS+ |         | BAP+/PD+ |         | VAS+/PD+ |         |
|----------------------------------|-----------|---------|----------|---------|----------|---------|
|                                  | n         | P value | n        | P value | n        | P value |
| Before therapy                   | 40        | 1.000   | 35       | 0.0063  | 35       | 0.5620  |
| After first therapy cycle        | 40        | 0.6225  | 35       | 0.6176  | 35       | 0.0751  |
| After second therapy cycle       | 22        | 0.4701  | 21       | 0.0263  | 21       | 1.000   |
| After third therapy cycle        | 9         | 1.000   | 9        | 1.000   | 9        | 1.000   |
| At the end of all therapy cycles | 40        | 1.000   | 35       | 0.0290  | 35       | 1.000   |



Conclusions: The lack of association between VAS+ and PD+ or BAP+ may be due to the difficulty of the patients in identifying and quantifying the pagetic pain, and suggests the weakness of the clinical criteria in defining the disease activity. Otherwise, PD technique proves to be a fast, reliable and not expensive tool, which is also very useful for monitoring/achieving better control of Paget's disease of bone.

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AB1007

# THE SLE-KEY® TEST DETECTS AN SLE SEROLOGIC SIGNATURE THAT PERSISTS OVER TIME AND IS INDEPENDENT OF DISEASE ACTIVITY

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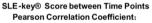
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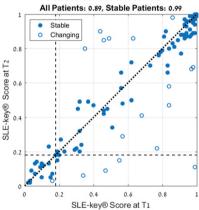
Background: We previously described the SLE-key® RuleOut test1,2 to rule out the presence of systemic lupus erythematosus (SLE) with 94% sensitivity, 75% specificity, and 93% negative predictive value. We also reported that the SLE-key® signature appeared to be independent of disease activity or duration<sup>3</sup> suggesting<sup>4</sup> that that the SLE-key® signature might persist over time in the same subject.

Objectives: Here we report that the SLE-key® signature remains stable over time in paired samples drawn from most individual subjects, regardless of disease

Methods: We determined the SLE-key® RuleOut scores for 113 paired serum samples submitted by clinics specializing in SLE. SLEDAI scores at the time of the blood draw ranged from 0 to 22. The mean SLEDAI difference within the pairs was 2.7±6.3. Samples were collected from subjects with a T1-T2 time difference that ranged from 0 to 11.5 years (mean =2±2.6 years).

Results: The SLE-Key® RuleOut test identifies an SLE-specific signature based on a profile of autoantibodies to a combination of nucleic acids (complex ssDNA and a defined oligonucleotide) and protein biomarkers. Patients with an SLE-key® score of >0.18 are considered not ruled out for a diagnosis of SLE. In 84% of paired samples, patients' SLE-key® scores remained essentially the same (Figure 1, closed circles). The scores for these subjects were stable, persistent, and independent of SLEDAI score or time between sampling. Significant changes in the SLE-key® scores of 18/113 patient pairs (open circles) appear to be independent of time between blood draws and change in SLEDAI score. In 7 cases there was a change in Rule Out status of the patients. In 3 cases, both scores were close to the 0.18 threshold and the change was deemed not significant. In 4 cases, patients' status changed from RuledOut to Not Ruled Out, but with no correlation to change in SLEDAI score or time between sampling dates. Records of patients with changing SLE-key® scores are being studied to determine the reasons and the clinical implications of the change.





Conclusions: The SLE-key® RuleOut test detects a serologic signature which remains stable between sampling dates and over a long period of time after diagnosis in 84% of subjects. Subjects who were ruled out at T1 were generally ruled out at T2. Patients not ruled out at T1 remained not ruled out at T2. The clinical implications of a changing SLE-key® RuleOut score in the remaining 16% of patients may be meaningful, and are currently being carefully investigated.

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## AB1008 DISTRIBUTIONS OF ANTIBODIES IN SLE PATIENTS IN **DIFFERENT ETHNIC GROUPS IN XINJIANG**

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Objectives: The aim of this study was to explore distributions of antibodies in SLE patients in different ethnic groups in xinjiang.