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Title: Endosonography vs. conventional bronchoscopy for the diagnosis of sarcoidosis: A randomized controlled trial

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Body: Background Tissue verification of non-caseating granulomas is recommended for diagnosing sarcoidosis. Granulomas can be detected by transbronchial lung biopsies at bronchoscopy (guideline standard) or alternatively by endosonography with fine-needle aspiration of intrathoracic lymph nodes. The current standard has limited diagnostic yield and is associated with pulmonary hemorrhage and pneumothoraces. Methods A randomized controlled trial to compare both diagnostic methods performed in 14 hospitals in 6 countries between 3/2009 and 11/2011. Patients with suspected sarcoidosis stage I/II in whom tissue verification was indicated were randomly assigned to bronchoscopy with transbronchial and endobronchial biopsies (arm A) or endosonography-guided fine-needle aspiration of mediastinal/hilar lymph nodes (arm B). Additionally, all patients underwent bronchoalveolar lavage (BAL). The primary end point was the detection of granulomas. Results 149 patients were randomized to bronchoscopy, 155 to endosonography. Significantly more granulomas were found in arm B (114 patients, 74%) versus arm A (72 patients, 48%) ($p<0.01$). Sensitivity to detect granulomas for arm B was 80% (95% CI, 73%-86%); for arm A 53 % (95% CI, 45%-61%). Sensitivity of the BAL for sarcoidosis based on CD4/CD8 ratio was 54% (95% CI, 46%-62%) for flow-cytometry; 24% (95% CI, 16%-34%) for cytospin analysis. Two serious adverse events occurred in arm A, one in arm B; all patients recovered completely. Conclusions Endosonography with nodal aspiration is superior to bronchoscopy with transbronchial and endobronchial biopsies for the assessment of granulomas in patients with sarcoidosis stage I/II.