

# Respiratory

## RESEARCH REVIEW™

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Issue 177 – 2020

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#### Abbreviations used in this issue

**FVC** = forced vital capacity  
**ILD** = interstitial lung disease  
**IPF** = idiopathic pulmonary fibrosis  
**TBLC** = transbronchial lung cryobiopsy

**Welcome** to this Respiratory Research Review with the topic of **ILD (interstitial lung disease)**. The topic is quickly becoming so large that a selection of only ten articles is likely to be nonrepresentative of the field. The theme of the articles selected, many of them with significant Australian/NZ input or lead, are reviews and areas needing improvement.

Three important review articles will assist the reader to maintain an **overview** of the field of ILDs. Peter George and Athol Wells provide a great service with their 'Contemporary concise [review](#) 2019: interstitial lung disease'. Highlights for me were the confirmation that in clinical settings, surgical lung biopsies are performed far less often than suggested by international guidelines, and within the network of a multidisciplinary meeting, simple transbronchial lung biopsies make meaningful contributions to the decision-making process. Also, the observations that nocturnal hypoxia, hiatus hernia and an increased right-to-left ventricular ratio are all markers of poor prognosis. Marlies Wijsenbeek and Vincent Cottin provide a very readable concise [overview](#) of the 'Spectrum of fibrotic lung diseases', which includes IPF (idiopathic pulmonary fibrosis), scleroderma-related ILD, rheumatoid arthritis-related ILD, stage IV sarcoidosis, chronic fibrotic hypersensitivity pneumonitis and unclassifiable fibrotic lung disease. The third paper that assists us sorting information is the 'Interstitial lung abnormalities detected incidentally on CT: a [position paper](#) from the Fleischner Society'. It defines areas not related to ILD like atelectasis, focal paraspinal fibrosis and findings related to aspiration. Subpleural fibrosis can be an early sign of ILD that progresses in 20% of patients in 2 years and 40% of patients in 5 years. The paper gives guidance in identifying risk factors and makes suggestions for management and monitoring.

Three areas **needing improvement** or blind spots include the outstanding [short review](#), with accompanying [scientific letter](#) and [editorial](#), on 'Silica-associated lung disease: an old-world exposure in modern industries'. The accompanying [scientific letter](#) on 'Stonemasons with silicosis: preliminary findings and a warning message from Australia' notes that artificial stones contain more than 90% silica compared with natural stones, which contain 2–30% silica. In Queensland alone, 141 claims of 659 stonemasons have been accepted. At highest risk are people who work with artificial stone, don't use personal protective equipment and perform dry-cutting techniques. Another blind spot or unconscious bias may be gender inequity when diagnosing, treating or researching ILD. Deborah Assayag and colleagues [report](#) on the 'Patient gender bias on the diagnosis of idiopathic pulmonary fibrosis' indicating that IPF is underdiagnosed in women and overdiagnosed in men. Leticia Kawano-Dourado and colleagues [point out](#) that despite women accounting for at least 50% of medical school graduates in the last two decades, women are under-represented as professors, conference presenters and authors of peer-reviewed articles. The [final blind spot](#) may be the effect of 'Income and other contributors to poor outcomes in U.S. patients with sarcoidosis'. Yvette Cozier and Praveen Govender provide a deep reflection on the impact of household income and geographical region on clinical outcomes in their [editorial](#), 'Sarcoidosis: an ill-afforded disease'.

Thank you again for the feedback and communication around the Research Review publications. We hope you enjoy the selection of articles even if you don't deal with ILD on a daily basis. In that case, the [wisdom of the Diffuse Lung Disease Network Steering Committee](#) may be helpful for the 'Preoperative evaluation of patients with interstitial lung disease'. They have adopted the ARISCAT (Assess Respiratory Risk in Surgical Patients in Catalonia) index and provide helpful guidance.

Kind regards,

**Professor Lutz Beckert**

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## Diagnostic likelihood thresholds that define a working diagnosis of idiopathic pulmonary fibrosis

**Authors:** Walsh SLF et al.

**Summary:** These researchers queried an international cohort of 404 respiratory physicians who each evaluated 60 cases of ILD to investigate the frequency that they advocated surgical lung biopsy in patient subgroups according to the likelihood of IPF and the risk associated with surgical lung biopsy, and also to determine the diagnostic likelihood at which the physicians would prescribe antifibrotic therapy when requesting surgical lung biopsy. The differential diagnosis included IPF in 41.1% of the 24,240 physician-patient evaluations, with surgical lung biopsy requested in 8.1%, 29.6% and 48.4% of cases with definite, provisional high-confidence and provisional low-confidence diagnoses of IPF, respectively. Antifibrotic therapy was prescribed without a request for surgical lung biopsy in 63.0% of provisional high-confidence IPF diagnoses. There was no significant difference between cases with definite versus provisional high-confidence diagnoses of IPF for mortality (hazard ratio 0.97 [95% CI 0.90, 1.04]).

**Comment:** Surgical lung biopsies are performed far less frequently than the international guidelines suggest; some of this is driven by the patient's comorbidities and surgical risks. Several of us participated in this international study where 404 physicians evaluated 60 cases of patients with ILD to detect our 'clinical threshold' on when to proceed to a lung biopsy. Overall, a biopsy was requested in only a minority of patients and not if a clinical likelihood of IPF of about 70% could be achieved. **Bottom line: most respiratory physicians managing IPF prescribe antifibrotic therapy without requesting a surgical lung biopsy.**

**Reference:** *Am J Respir Crit Care Med* 2019;200:1146–53  
[Abstract](#)

## Diagnostic accuracy of transbronchial lung cryobiopsy for interstitial lung disease diagnosis (COLDICE)

**Authors:** Troy LK et al., on behalf of the Cryobiopsy versus Open Lung biopsy in the Diagnosis of Interstitial lung disease alliance (COLDICE) Investigators

**Summary:** Patients aged 18–80 years with ILD requiring histopathological evaluation and who were referred for lung biopsy (n=65) underwent sequential TBLC (transbronchial lung cryobiopsy) and surgical lung biopsy in the prospective COLDICE study. Histopathological agreement between TBLC and surgical lung biopsy was 70.8%, whereas diagnostic agreement at multidisciplinary discussion was 76.9%. For TBLCs with high or definite diagnostic confidence at multidisciplinary discussion (65 cases), 95% were concordant with the surgical lung biopsy diagnoses. Among 26 of the 65 cases with low-confidence or unclassifiable TBLC diagnoses, surgical lung biopsy reclassified 23% to alternative high-confidence or definite multidisciplinary discussion diagnoses. Mild or moderate airway bleeding associated with TBLC was recorded for 22% of the patients. One patient died after an acute IPF exacerbation.

**Comment:** Guidelines recommend a surgical lung biopsy in up to 30% of cases, which has a reported mortality risk of about 1.7%. TBLCs have emerged. Our Australian colleagues report on their comparative, multicentre prospective study, in which 65 patients had both an open lung biopsy and a TBLC in the same setting. One of the patients died within 90 days, i.e. 2% mortality. The patients were discussed twice at the lung multidisciplinary meeting, once with the open lung biopsy and once with the TBLC results. **Bottom line: TBLC is a valid first-line minimally invasive diagnostic tool for patients with ILD who require a lung biopsy.**

**Reference:** *Lancet Respir Med* 2020;8:171–81  
[Abstract](#)

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## Serial CT analysis in idiopathic pulmonary fibrosis: comparison of visual features that determine patient outcome

**Authors:** Jacob J et al.

**Summary:** Separate pairs of radiologists scored paired volumetric CTs obtained 6–24 months from baseline for two cohorts of patients with IPF to determine if visual CT variables could help confirm whether marginal FVC declines represent genuine clinical deterioration as distinct from measurement noise. A univariate analysis showed that with the exception of ground-glass opacities, changes to all CT variables were predictors of mortality in both cohorts. A multivariate analysis confirmed that change in traction bronchiectasis severity predicted mortality independently of FVC decline. Interobserver agreement between scorer pairs was good for change in traction bronchiectasis severity. For all patients with marginal FVC declines, change in traction bronchiectasis severity was an independent predictor of mortality, and was able to identify more patients with deterioration than the change in the extent of honeycombing.

**Comment:** Progression of IPF has been defined as a loss in the FVC by more than 10%. Marginal declines in the FVC between 5% and 10% could be due to partial treatment response, physiological variation in the measurement or possible technical issues. These authors from Utrecht and London reviewed serial CT scans 6–24 months apart of two patient cohorts looking for radiological predictors of mortality. **Bottom line: worsening of traction in bronchiectasis identified patients with disease progression, even if their lung function only showed a marginal decline.**

**Reference:** *Thorax* 2020;75:648–54

[Abstract](#)

## Pamrevlumab, an anti-connective tissue growth factor therapy, for idiopathic pulmonary fibrosis (PRAISE)

**Authors:** Richeldi L et al.

**Summary:** Patients (including from NZ) with IPF and predicted FVC percentage of  $\geq 55\%$  were randomised to intravenous pamrevlumab 30 mg/kg (n=50) or placebo (n=53) every 3 weeks over a 48-week period in the phase 2 PRAISE trial. Compared with placebo, pamrevlumab was associated with a smaller decline from baseline in predicted FVC percentage at week 48 (primary efficacy outcome;  $-2.9\%$  vs.  $-7.2\%$  [ $p=0.033$ ]) and a smaller proportion of participants who experienced disease progression ( $10.0\%$  vs.  $31.4\%$  [ $p=0.013$ ]). The respective treatment-emergent serious adverse event rates in the pamrevlumab and placebo arms were 24% and 15%, with three and seven participants from the respective arms discontinuing treatment. None of the on-study deaths were considered to be related to treatment.

**Comment:** This is another study in which several NZ patients had the opportunity to participate. It was a safety study of a monoclonal antibody against the connective tissue growth factor that mediates the fibrotic process. The agent passed the safety study with flying colours. Indeed, it was so well tolerated that it was impossible to tell if the participant was on active treatment or placebo; the main reported side effects were related to setting up the infusion. This study showed an early signal of significantly reducing the loss of lung function. **Bottom line: pamrevlumab is a promising biological agent, which needs to be tested in the ongoing phase 3 trial.**

**Reference:** *Lancet Respir Med* 2020;8:25–33

[Abstract](#)

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## Nintedanib in patients with progressive fibrosing interstitial lung diseases – subgroup analyses by interstitial lung disease diagnosis in the INBUILD trial

**Authors:** Wells AU et al., on behalf of the INBUILD trial investigators

**Summary:** The INBUILD trial randomised patients with fibrosing ILDs other than IPF to receive nintedanib 150mg twice daily or placebo for  $\geq 52$  weeks in a 1:1 ratio; the trial recruited 173 patients with chronic hypersensitivity pneumonitis, 170 with an autoimmune ILD, 125 with idiopathic nonspecific interstitial pneumonia, 114 with unclassifiable idiopathic interstitial pneumonia and 81 with other ILDs. Compared with placebo, nintedanib had a consistent effect of reducing the rate of FVC decline across the five subgroups of ILD diagnosis (68.3–197.1 mL/year;  $p=0.41$  for treatment by subgroup by time interaction). Adverse events reported in the subgroups were similar to those reported for the overall study population.

**Comment:** The last time I was able to attend an international conference, this subgroup analysis of the INBUILD trial was presented as one of the major highlights. Nintedanib and pirfenidone are currently both licensed for the treatment of IPF. This is a predetermined subgroup analysis of patients with other fibrotic lung diseases ([N Engl J Med 2020](#)). The numbers are small; however, the trend of reducing the loss of vital capacity is rather convincing albeit small. **Bottom line: antifibrotic agents, in particular nintedanib, may be beneficial in treating chronic, progressive ILD.**

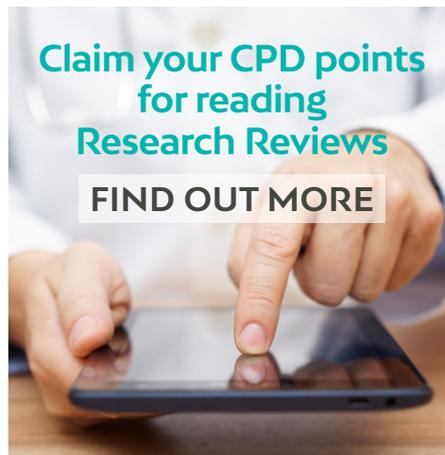
**Reference:** *Lancet Respir Med* 2020;8:453–60  
[Abstract](#)

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## Patient expectations, experiences and satisfaction with nintedanib and pirfenidone in idiopathic pulmonary fibrosis

**Authors:** Moor CC et al.

**Summary:** Ninety outpatients with IPF prospectively completed the Patient Experiences and Satisfaction with Medication questionnaire to assess their expectations, experiences and satisfaction of their antifibrotic treatment (43% nintedanib and 57% pirfenidone) in this quantitative study. Responses after 6 months of treatment showed a mean overall satisfaction with medication score of 2.1. There were no significant differences between nintedanib and pirfenidone recipients for experiences and satisfaction with medication, or for the number and severity of side effects. The respondents rated perceived effectiveness as more important than side effects and ease of use ( $p=0.001$ ), and their expectations regarding effectiveness were greater than experiences after 6 months. The main factor associated with overall medication satisfaction was self-reported experience with effectiveness.

**Comment:** This is a fascinating study from Rotterdam with 90 participants who were asked about their expectations, experiences and satisfaction with antifibrotic treatment at baseline, 3 months and 6 months. About half were taking nintedanib and half pirfenidone. The self-reported experiences with the effectiveness of the medication, like physical health or daily activities, was the main factor associated with medication satisfaction. In contrast, a quarter of the surveyed healthcare providers considered side effects to be more important than the risk of disease progression. **Bottom line: patients' experiences and satisfaction with antifibrotic medication were relatively positive despite side effects.**

**Reference:** *Respir Res* 2020;21:196  
[Abstract](#)

## Nintedanib and sildenafil in patients with idiopathic pulmonary fibrosis and right heart dysfunction

**Authors:** Behr J et al., on behalf of the INSTAGE Trial Investigators

**Summary:** These authors performed a prespecified subgroup analysis of data from the INSTAGE randomised controlled trial, which showed that combining nintedanib with sildenafil in patients with IPF and severely impaired gas exchange improved SGRQ (St. George's Respiratory Questionnaire) total scores and BNP (brain natriuretic peptide) levels and slowed FVC decline compared with nintedanib. In this subgroup analysis, no significant differences were detected between participants with ( $n=117$ ) versus without ( $n=156$ ) echocardiographic signs of right heart dysfunction at baseline with respect to the effects of nintedanib plus sildenafil versus nintedanib alone on changes in SGRQ and FVC decline, but participants with right heart dysfunction derived a greater benefit from combination therapy for stabilising BNP levels.

**Comment:** Many of our patients with IPF are short of breath and pulmonary hypertension is a sign of severity. Several studies have examined the effect of vasodilator therapy with sildenafil in patients with IPF, which have all been largely negative. This is a subgroup analysis on the patients with severe right ventricular dysfunction, who had been offered sildenafil in addition to treatment with nintedanib. Steven Nathan has written an excellent [editorial](#) and reminds us that the increased pulmonary pressure could be an adaptive phenomenon, so treatment may actually cause harm. **Bottom line: sildenafil had no additional benefit in patients with IPF on nintedanib.**

**Reference:** *Am J Respir Crit Care Med* 2019;200:1505–12  
[Abstract](#)



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### Independent commentary by Professor Lutz Beckert

Professor Lutz Beckert is the Associate Dean Medical Education with the University of Otago, Christchurch. He is also a Respiratory Physician at Canterbury District Health Board with particular clinical interests in interstitial lung disease, pulmonary vascular disease, respiratory physiology and COPD (chronic obstructive pulmonary disease). Lutz is happy to be contacted to discuss research ideas either as a sounding board or with the view of future collaborations.





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## Opportunities to diagnose fibrotic lung diseases in routine care

**Authors:** Jones MG et al., on behalf of the Respiratory Effectiveness Group's Interstitial Lung Disease Working Group

**Summary:** Trends in respiratory symptoms and lower respiratory healthcare resource use during the 10 years prior to a diagnosis of pulmonary fibrosis were reported for a primary care cohort of 2223 patients. A progressive increase in healthcare resource use was seen across multiple lower respiratory-related domains during the 10 years prior to pulmonary fibrosis diagnosis, with 18% of patients having records of multiple healthcare contacts for lower respiratory complaints 5 years before diagnosis, increasing to 79% in the year before diagnosis (including 38% having  $\geq 5$  healthcare contacts).

**Comment:** With the event of effective antifibrotic treatments, an early diagnosis of IPF may provide significant clinical benefits to the patient. These British authors used the Optimum Patient Care Research Database to identify about 2000 patients with IPF. They then went back over the datapoints of contact with the healthcare system for any reason, like antibiotic, inhaler or steroid prescribing. Healthcare utilisation increased significantly over the years prior to the diagnosis of IPF. **Bottom line: by focussing on the number of presentations, cough and breathlessness, many patients could have been diagnosed about 2 years earlier.**

**Reference:** *Respirology*; Published online May 11, 2020

[Abstract](#)

## Artificial stone-associated silicosis in China: a prospective comparison with natural stone-associated silicosis

**Authors:** Wu N et al.

**Summary:** The natural histories of artificial and natural stone-associated silicoses were compared in this research. Compared with individuals with a diagnosis of natural stone-associated silicosis ( $n=63$ ), those diagnosed with artificial stone-associated silicosis ( $n=18$ ), had a substantially shorter median duration of exposure prior to symptom onset (6.4 vs. 29.3 years [ $p<0.01$ ]), with four of the patients with artificial stone-associated silicosis exhibiting rapid deterioration in lung function over the 6- to 12-month follow-up period: prebronchodilator FVC fell by 587 mL/year and FEV<sub>1</sub> (forced expiratory volume in 1 second) fell by 625 mL/year. The patients with artificial stone-associated silicosis also more frequently had ground-glass opacification, progressive massive fibrosis, emphysema and pulmonary artery widening on CT than their counterparts with natural stone-associated silicosis. Compared with the patients with natural stone-associated silicosis, patients with artificial stone-associated silicosis were more likely to be candidates for lung transplantation (~38.9% vs. 3.2% [ $p<0.01$ ]) or die (27.8% vs. 0% [ $p<0.01$ ]).

**Comment:** This article should be read with the review article and editorial linked in the introduction. In this retrospective review of the 81 patients who were diagnosed with silicosis in Beijing, the authors compared the 18 patients who developed silicosis after working with artificial stones with the 63 who worked with natural stone. Patients working with artificial stone were a mean age of 36 years, had 6 years to the onset of illness and had more extensive CT abnormalities, and 39% qualified for a lung transplant and 28% died. **Bottom line: artificial stone-associated silicosis is characterised by shorter latency, rapid radiology progression and accelerated loss of lung function.**

**Reference:** *Respirology* 2020;25:518–24

[Abstract](#)

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## Income and other contributors to poor outcomes in U.S. patients with sarcoidosis

**Authors:** Harper LJ et al.

**Summary:** The relationship between income and sarcoidosis outcome after controlling for socioeconomic and disease-related factors was explored using data from 2318 patients with the condition in this US research. A multivariate analysis revealed that compared with patients with high annual incomes ( $\geq$ USD85,000), those with low and middle incomes ( $<$ USD35,000 and USD35,000–84,999, respectively) were more likely: i) to develop new sarcoidosis-related comorbidities (respective odds ratios 2.4 [CI 1.7, 3.3] and 1.4 [1.1, 1.9]); ii) to develop new steroid-related comorbidities (1.3 [0.9, 2.0] and 1.5 [1.1, 2.1]); iii) to experience a greater impact on family finances (7.9 [4.9, 12.7] and 2.7 [1.9, 3.9]); and iv) to have lower health-related quality of life ( $p<0.001$ ). The low-income patients also had greater use of supplemental oxygen and a greater need for assistive devices, and experienced more job losses. Nearly two-thirds of patients (63%) developed comorbidities after their sarcoidosis diagnosis, which was a strong independent predictor of poor outcomes. Income was consistently a strong predictor of outcome in random forest models.

**Comment:** This is quite a sobering prospective study utilising an online tool of more than 2000 patients who were diagnosed with sarcoidosis in the US. Even after correcting for insurance status, patients with lower incomes were more likely to develop new sarcoidosis or sarcoidosis-related comorbidities, had a worse quality of life and experienced a greater negative effect on their family finances. This study design can't answer if patients with fewer resources had more exposure to disease-aggravating factors or less access to treatment. **Bottom line: improvements in sarcoidosis outcomes are possible and necessary, so that a lower income won't affect a large number of patients.**

**Reference:** *Am J Respir Crit Care Med* 2020;201:955–64

[Abstract](#)

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