Selexipag for inoperable CTEPH: why meeting a primary endpoint simply isn't enough

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Though this study met its primary endpoint and oral selexipag was approved as a treatment for inoperable CTEPH patients in Japan, the overall results and scope of this study do not justify a valid position for selexipag in the treatment armamentarium. https://bit.ly/3INAYgO

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In the current issue of the *European Respiratory Journal*, Ogo *et al.* [1] report the results of a randomised, placebo-controlled, multicentre trial (RCT) from Japan, in which the effects of selexipag in patients with inoperable chronic thromboembolic pulmonary hypertension (CTEPH) were investigated. All patients had previously been treated by either surgery (*i.e.* pulmonary endarterectomy; PEA) or intervention (*i.e.* balloon pulmonary angioplasty; BPA) [2], and were suffering from persistent or recurrent pulmonary hypertension. The primary objective of the trial was the change in pulmonary vascular resistance (PVR). In fact, PVR was significantly reduced; however, the effect was at best moderate, and notably many relevant secondary endpoints, such as the 6-min walking distance (6MWD), serum N-terminal pro-brain natriuretic peptide (NT-proBNP), and World Health Organization functional class did not change in a meaningful manner. The adverse events profile corroborated the known side-effect profile of selexipag, as previously reported from trials in the field of pulmonary arterial hypertension (PAH). Based on the results of this study, selexipag was approved for patients with inoperable CTEPH in Japan.