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LETTER

Patient-reported outcome measures (PROMs) using the MASK-air® app in severe asthma

To the Editor,

Patient-reported outcome measures (PROMs) are increasingly used. They improve shared decision making, symptom management, patient satisfaction and quality of life.[1] PROMs must be carefully defined and accurately measured to capture relevant patient information and to allow them to be compared with other measurements. PROMs may concern signs, symptoms, physical functioning (e.g. sleep), social functioning (e.g. work performance) and others.[2]

The MASK-air® (Mobile Airways Sentinel networK for airway diseases) app is a DG Santé Good Practice for digitally-enabled, patient-centred care in rhinitis and asthma multimorbidity.[3] PROMs in MASK-air® include visual analogue scales (VASs) assessing daily global allergy symptoms, nose, eye and asthma symptoms, dyspnoea, and impact of allergy on work and sleep. These VASs have not been tested in severe asthma. When the study was initiated, severe asthma was defined as a condition requiring the Global Initiative for Asthma (GINA) 4 or 5 level of medications to be controlled or which remains uncontrolled despite that treatment.[4] As an add-on therapy to inhaled corticosteroids and long-acting β-agonists, GINA recommends tiotropium (long-acting anti-muscarinic agent: LAMA) for patients at Steps 4–5 and biologics for those at Step 5.[5]

In this study, we aimed to assess the correlation between VAS asthma and other MASK-air® daily reported PROMs in severe asthmatic patients with nasal symptoms. Considering the definition of severe asthma when this study was initiated, we included daily monitoring data from MASK-air® users aged 16–90 years self-reporting at least 1 day of ICS-LABA+LAMA and/or omalizumab use. We analysed data from 21 May, 2015 to 6 December, 2020 (Appendix S1; Tables S1 and S2).[3]

Among the 17,780 MASK-air® users, 86 met the inclusion criteria and were enrolled (age range: 18–80 years). Twenty-six reported at least 1 day of omalizumab use (with or without LAMAs). A total of 2473 days were reported for patients using omalizumab at least once compared with 2349 days for the remaining participants (averages: 95.1 and 39.2 days per patient) (Table S2).

The correlations between PROMs are shown in Table 1, Figure 1 and Figure S1. Strong correlations were found between VAS asthma and other VASs. The Spearman correlation coefficient between VAS asthma and VAS dyspnoea was 0.898. In addition, to account for the existence of different observations by the same users, repeated measures correlation coefficients were calculated.[6] The repeated measures correlation coefficients were strongest for the associations between VAS asthma and dyspnoea ($\rho = 0.713$), combined symptom-medication score ($\rho = 0.747$) and work ($\rho = 0.658$).

As in any real-world data app study, several common limitations should be considered.[3] Moreover, in this study, there were no diagnoses of asthma reported by physicians or by pulmonary function test. However, patients treated with omalizumab and LAMAs are likely to be asthmatic patients at GINA Steps 4–5, even though we may not exclude other diseases (e.g. LAMA for chronic obstructive pulmonary disease). Another limitation corresponds to the relatively small number of included participants (particularly compared with the number of MASK-air® users), resulting in a lower precision of our estimates.

TABLE 1 Correlation coefficients between different PROMs in severe asthma

	N observations	Spearman correlation coefficient (95% CI)	Repeated measures correlation coefficient (95% CI)[5]
VAS asthma *vs* VAS dyspnoea	1862	0.898 (0.879;0.915)	0.713 (0.690;0.735)
VAS asthma *vs* VAS global	4822	0.767 (0.750;0.784)	0.544 (0.524;0.564)
VAS asthma *vs* VAS nose	4822	0.755 (0.738;0.771)	0.465 (0.443;0.487)
VAS asthma *vs* VAS eyes	4822	0.640 (0.620;0.661)	0.378 (0.354;0.402)
VAS asthma *vs* VAS work	1840	0.768 (0.739;0.793)	0.658 (0.631;0.683)
VAS asthma *vs* VAS sleep	4168	0.637 (0.613;0.658)	0.339 (0.312;0.366)
VAS asthma *vs* CSMS	4822	0.875 (0.865;0.884)	0.747 (0.734;0.759)

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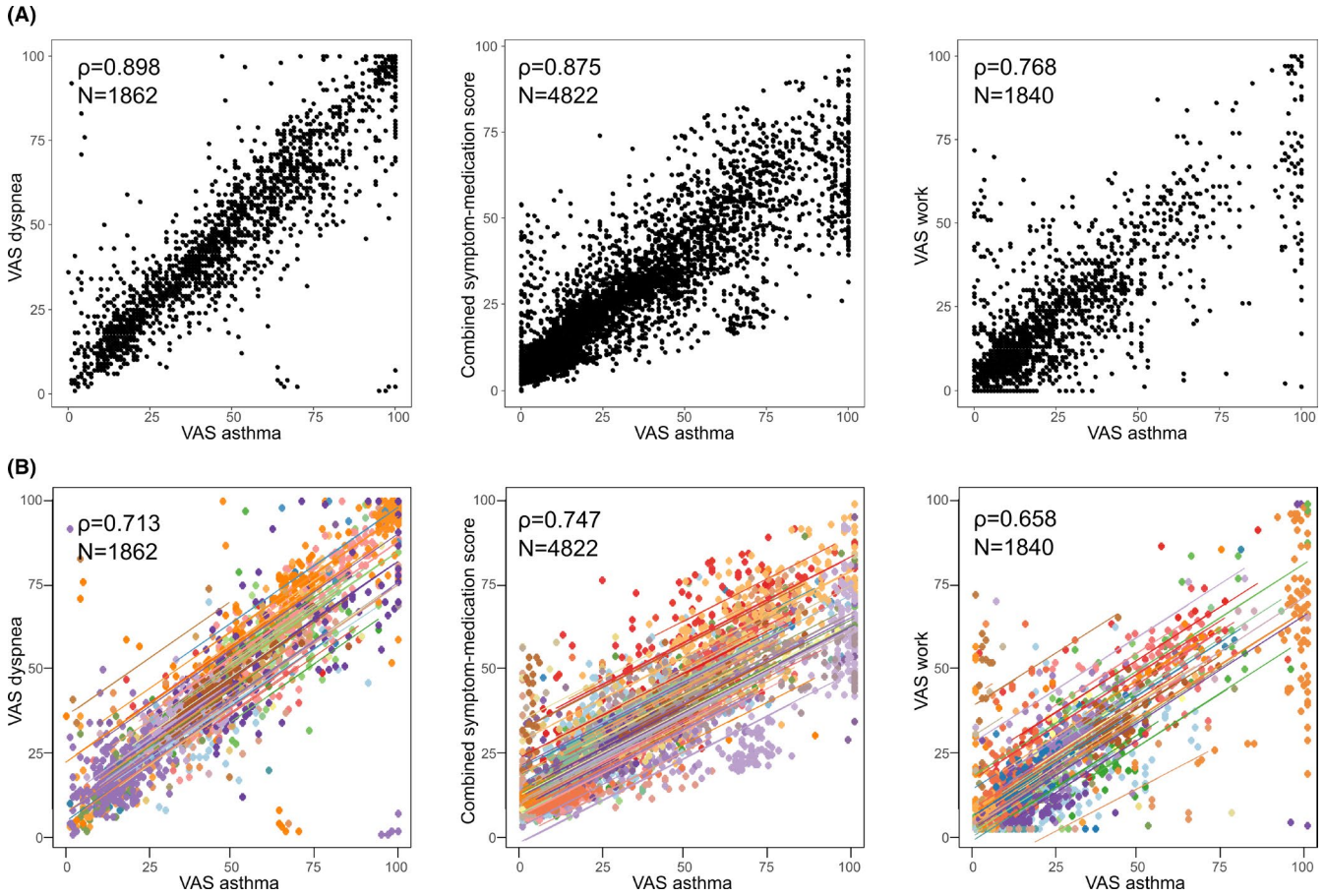

FIGURE 1 Correlations between the visual analogue scale (VAS) assessing the severity of asthma symptoms ('VAS asthma') and (i) VAS dyspnoea, (ii) the combined symptom-medication score and (iii) VAS work. A—Spearman rank correlation coefficients; B—Repeated measures correlation coefficients

VAS asthma appears to be an interesting PROM in severe asthma. It is strongly correlated with VAS dyspnoea. The latter may therefore not necessarily be useful for inclusion in MASK-air®, even in this severe form of asthma. VAS asthma was more strongly correlated with other PROMs related to lower airways or to functional domains (e.g. VAS work) than with PROMs related to rhinitis. This indicates good convergent and divergent validity. While results of this study point to a high validity of VAS asthma in severe asthma, future studies with larger samples are needed to assess other properties—including reliability and responsiveness—of this PROM.

CONFLICTS OF INTEREST

JB reports personal fees from Chiesi, Cipla, Hikma, Menarini, Mundipharma, Mylan, Novartis, Sanofi-Aventis, Takeda, Teva, Uriach, other from KYomed-Innov, personal fees from Purina, other from MASK-air, outside the submitted work.

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SUPPORTING INFORMATION

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