Liquid pediatric formulation of sildenafil citrate: Preparation and stability evaluation

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Sildenafil citrate, neonatal pulmonary antihypertensive, not being marketed as a pediatric drug, an extemporaneous liquid preparation of this drug could be proposed for a pediatric use. The objective of this study is therefore to prepare a solution of Sildenafil citrate, in a simple syrup (1.25 mg/ml), from Sildenafil Tablets (VIACATAL® 50 mg), according to a common practice “dosage adjustment” allowing to adjust doses in pediatrics.

A physicochemical and microbiological stability study of this solution was carried out at 5°C. The results of this study have shown that Sildenafil citrate syrup solutions stored in the refrigerator are stable for a period of 4 weeks: unchanged color and odor, no crystallization observed, no pH variation, unchanged active substance concentration and no microbial contamination detected. However, after opening the vials, these preparations must be used within 7 days.

Keywords Liquid pediatric formulation; Stability; Sildenafil citrate
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Right ventricle end-systolic remodeling index in patients with atrial septal defect and severe pulmonary arterial hypertension

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Background Outcome of patients with atrial septal defect (ASD) and severe pulmonary arterial hypertension (PAH) relates to right ventricular (RV) function. Magnetic resonance imaging (MRI) remains the gold standard for evaluating the RV function but it is not used routinely. We investigated the relationship between MRI and multiple echocardiography parameters, including the Right Ventricle End-Systolic Remodeling Index (RVESRI), a new prognostic marker in patients with PAH.

Methods Twenty-three patients with ASD and severe PAH (median age 49 year old [39–59], SpO2 92% [90–95], WHO functional class II or III, mean pulmonary artery pressure 51 mmHg [40–59]) were included between 2014 and 2018. All patients underwent MRI and echocardiography assessment. Echocardiographic measurements of RV remodeling and function included TAPSE, RV fractional area change (RVFAC), peak systolic velocity of the tricuspid valve (S’TV), right atrial (RA) area, RV strain, Systolic to diastolic ratio, eccentricity index and RVESRI, defined by septum length divided by lateral wall length (Fig. 1). Pericardial effusion was noted.

Results Median RV ejection fraction (EF) evaluated with MRI was 46% [34–59]. RV dysfunction (RVF < 45%) was observed in 43% of patients. Median RVFAC and RVESRI were 29.6% [23–34] and 1.6 [1.4–1.7] respectively. By spearman correlation, RVFAC and RVESRI were significantly correlated to RVEF (Rho 0.62, P < 0.007 and Rho – 0.51, P < 0.02 respectively). By linear regression, RVFAC and RVESRI were also correlated to RVEF (R2 = 0.36, P < 0.003 and R2 = 0.34, P < 0.08). Pericardial effusion was associated with RV dysfunction (P < 0.008) and a lower RVFAC (P < 0.01). TAPSE, S’TV and RV strain were not correlated with RVEF.

Conclusion RVFAC, RVESRI and pericardial effusion were markers of RV dysfunction in patients with ASD and severe PAH. RVESRI appears as a simple and reliable parameter for follow-up. Its prognostic value in patients with CHD remains to be demonstrated.

Keywords ASD-pulmonary hypertension-echocardiography

Fig. 1 Right ventricular end-systolic remodeling index (RVESRI) represent a simple ratio of end-systolic lateral length and septal height.

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