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DEVELOPMENT OF NEW INTERNATIONAL CLASSIFICATION CRITERIA FOR ANTIPHOSPHOLIPID SYNDROME: PHASE III CASE COLLECTION RESULTS

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Background: An international multi-disciplinary effort is underway to develop rigorous, new, consensus- and evidence-based classification criteria for Antiphospholipid Syndrome (APS). The methodological approach includes four phases; we have previously presented phases I and II (item generation and reduction), which resulted in 27 candidate criteria¹ organized in laboratory and clinical domains.

Objectives: Phase III (item weighting/threshold identification) is currently underway; here we report initial Phase III case collection results.

Methods: We used REDCap, a secure data system, for Phase III international case collection. The candidate criteria of 27 items at the end of Phase II was represented in a standardized case collection form. We asked international physicians interested in APS to provide and rate cases using a Likert scale (+3 to -3: highly likely to highly unlikely to be APS). Cases with higher scores (+2 or +3) were categorized as "highly likely" APS, whereas lower scores (+1 to -3) were categorized as "equivocal or unlikely" APS.

Results: We collected 314 potential APS cases (mean age 43.8±14.4 years; 79% female; and 77% white) between 6/2019-8/2019 from 17 sites in Europe (47%), North America (41%), and South America (11%). Majority of cases were potential primary APS (64%); 137 were rated as "highly likely" and 177 as "equivocal or unlikely" APS. Lupus anticoagulant, anti-β₂glycoprotein-I antibody IgG/M, anticardiolipin antibody IgG, arterial thrombosis, venous thromboembolism, microvascular disease, fetal loss between 16-34 weeks, severe preeclampsia, severe placental insufficiency, cardiac valve disease, and low platelet count occurred with higher frequency in the APS cases categorized as "highly likely" (Table).

Conclusion: International collection of cases spanning the spectrum of "highly likely" to "equivocal or unlikely" APS provide "real world" assessment of patients being referred for APS evaluation. In next steps, proposed candidate criteria will be further refined, organized, and weighted, and a preliminary threshold for APS classification will be determined.

Table. Characteristics of Potential APS Cases Categorized by Physician Assessment

Candidate Relative Criteria, n (%)	Total (n=314)	Highly Likely APS (n=137)	Equivocal or Unlikely APS (n=177)
LABORATORY			
Lupus Anticoagulant Test	208 (66)	117 (85)	91 (51)
Anticardiolipin Antibody			
• IgG	170 (54)	90 (66)	80 (45)
• IgM	138 (44)	61 (45)	77 (44)
Anti-β ₂ glycoprotein-I Antibody			
• IgG	99 (32)	66 (48)	33 (19)
• IgM	79 (25)	47 (34)	32 (18)
CLINICAL			
Macrovascular			
• Superficial Vein Thrombosis	15 (5)	4 (3)	11 (6)
• Venous Thromboembolism	95 (30)	63 (46)	32 (18)
• Transient Ischemic Attack	27 (9)	13 (10)	14 (8)
• Arterial Thrombosis	82 (26)	58 (42)	24 (14)
Microvascular*	86 (27)	62 (45)	24 (14)
Obstetric**			
• Embryonic Loss (<10 weeks [w])	85 (45)	34 (42)	51 (48)
• Fetal Loss (10w-16w)	20 (11)	9 (11)	11 (10)
• Fetal Loss (16w-34w)	42 (22)	32 (40)	19 (18)
• Severe Preeclampsia (<34w)	27 (14)	18 (22)	9 (8)
• Severe Placental Insufficiency (<34w)	22 (12)	13 (16)	9 (8)
Cardiac Valve Disease***	32 (10)	21 (15)	11 (6)
Thrombocytopenia <150 G/L	72 (23)	43 (31)	29 (16)

*Livedo racemosa, livedoid vasculopathy, adrenal hemorrhage, acute ischemic encephalopathy, cardiac microvascular disease, pulmonary hemorrhage, acute and/or chronic antiphospholipid-related nephropathy; **Total number of patients ever pregnant: 188 (highly likely APS: 81; unlikely APS: 107) ***Valve thickening and/or vegetation.

References:

[1] Barbhaiya M et al. Phase II Results [abstract]. Arthritis Rheumatol. 2019;71 (suppl 10).

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OP0098

TRAJECTORIES OF GROWTH IN OFFSPRING FROM MOTHERS WITH PREVALENT OR PRE-SYSTEMIC LUPUS ERYTHEMATOSUS: A NATIONWIDE POPULATION-BASED STUDY IN KOREA

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Background: Systemic lupus erythematosus (SLE) is an autoimmune disease that primarily affects women of childbearing age and is known to have poor maternal and fetal outcomes associated with pregnancy.

Objectives: We planned on the long-term follow-up studies to find out whether SLE offspring with low birth weight would properly catch up in future childhood life.

Methods: Korean National Health Insurance (NHI) service is a mandatory, single public health insurance system that covers more than 50,000,000 Korean population. It consists of inpatient and outpatient diagnosis and treatment data for the purpose of reimbursement. Rare and Intractable Diseases (RID) registration system is a copayment reduction scheme which provides financial support to patients with certain rare disease, include SLE. National Health Screening Program for Infants and Children (NSHPIC) is a population screening system for children aged 4 to 71 months, requiring 7 visits to participating clinic at pre-specified times.

Among the children who were born between 2008 and 2013, we identified those who completed the first (between 4-6th month), second (between 9-12th month) and either sixth or seventh examination (between 54-65th month and 66-71th month, respectively) of NSHPIC. By linking maternal and offspring healthcare data through their unique personal identification numbers, we constructed a mother-child database to track the growth of the child. Among their mothers, we could identify SLE patients who had given live singleton births using RID database (V136) and the international classification of disease code (M32.x) for SLE. Therefore, we were able to follow birth weight and subsequent growth of offspring according to their mother's disease status.

Results: We could identify 1,007 offspring from SLE mothers and 793,537 control from non-SLE mothers. Offspring from SLE mothers showed the higher risk of low birth weight defined as less than 2500g [hazard ratio (HR) 4.79, 95% confidence interval (CI) 4.08–5.63]. In terms of subgroups analysis according to the time of diagnosis, the risk of low birth weight was the highest in offspring from those who diagnosed SLE during pregnancy (HR 8.22, 95% CI 3.18–21.26). In addition, the risk of low birthweight increased not only in offspring from already diagnosed SLE before pregnancy (HR 5.63, 95% CI 4.41–7.19), but also in offspring from those who diagnosed with SLE after delivery (pre-SLE) compared to general population (HR 2.03, 95% CI 1.33–3.09).

Subsequent growth failure defined as less than 3 percentile was more prevalent in SLE offspring compared to general population at 4-6 month (HR 3.28, 95% CI 2.22–4.77). However, at 6-9 months and 54-71 months, the gap was reduced, showing no statistical difference with the general population (HR 1.22, 95% CI 0.73–2.03 and HR 1.26, 95% CI 0.88–1.80, respectively).

Among SLE offspring with low birth weight (< 2500g), 89.34% showed the body weight of 3 percentile or more and 75.84% showed the body weight 10 percentile or more at 4-6 month. The proportion of children who catch up afterwards has not increased since then, as the proportion of children who