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Congress Abstracts

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BACKGROUND AND AIMS: Metabolic biomarkers are of high importance for the identification of early renal involvement in the course of type 2 diabetes mellitus (DM). Gangliosides, which are complex cell type-specific glycosphingolipids, consist of a sialylated oligosaccharide chain attached to a ceramide of different composition with respect to the sphingoid base and fatty acid residues [1]. Gangliosides play a major role in the pathogenesis of diabetic kidney disease (DKD). The aim of the study was to assess the pattern of urinary gangliosides in patients with type 2 DM.
METHOD: The urine gangliosidome of 30 type 2 DM patients (10 normo-, 10 micro-, and 10 macroalbuminuric) has been investigated in a cross-sectional pilot study, by a comparative assay with 10 healthy controls. Following the optimization of urine ganglioside extraction procedure [2, 3], we have determined the composition of native ganglioside mixtures from the 24-h collected urine samples using a modern bioanalytical platform based on nanoelectrospray ionization (nanoESI) high-resolution mass spectrometry (HR MS) on an Orbitrap instrument.
RESULTS: HR MS screening and fragmentation analysis by tandem MS revealed that: (i) the urinary gangliosidome of type 2 DM patients contains a significantly higher number of distinct species differing in either their glycan or ceramide structure than the controls; (ii) the ganglioside urinary level was significantly increased in normoalbuminuric patients compared with healthy control subjects; (iii) the gangliosidome of macroalbuminuric patients is characterized by an elevated overall sialic acid content than normo- and microalbuminuric diabetics and more complex structures, including fucosylated, O-GalNAc- and CH_3COO^--modified compounds; (iv) the degree of sialylation of species presented correlations with the level of albuminuria and renal function; (v) further detailed structural analysis of a type GQ1(d18:1/18:0) species (identified only in macroalbuminuric patients) demonstrated that the present isomer is of type D (all four syalic acids are linked to the inner galactose).
CONCLUSION: HR MS by tandem MS methods, using an Orbitrap instrument, are a reliable tool for the identification of a particular ganglioside profile in the urine of type 2 DM patients. The sialylated species and those altered by peripheral attachments to the glycan core might be considered useful indicators of early DKD.

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HOW TO PREVENT GENITAL INFECTIONS IN POST-MENOPAUSAL WOMEN WITH TYPE 2 DIABETES MELLITUS UPON INITIATION OF SODIUM–GLUCOSE COTRANSPORTER-2 (SGLT2) INHIBITORS: A REAL-LIFE MULTI-CENTER OBSERVATIONAL STUDY

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BACKGROUND AND AIMS: Patients with type 2 diabetes mellitus (T2DM) often discontinue sodium–glucose cotransporter-2-inhibitors (SGLT2 i) despite high efficacy and safety due to genital infection (GI).

SGLT2i, also called gliflozins, represent the newest class of anti-hyperglycemic agents [1] whose effects depend on the ability to dramatically reduce the threshold for maximum glucose tubular resorption rate in patients with type 2 diabetes mellitus (T2DM), with consequently enhanced glycosuria. Due to elevated urinary glucose output, T2DM increases the risk for urinary tract infections (UTIs) and non-sexually transmitted genital infections (GIs) [15]. Massive glycosuria might, indeed, already cause commensal genital microorganism overgrowth in people with T2DM [16] and is likely to increase the risk for GIs and UTIs when further aggravated by SGLT2i. To assess real-life GI risk profile in post-menopausal T2DM patients educated on strict hygiene-based prevention practices (SHBPPs) due to their intrinsic GI susceptibility.
METHOD: 21 post-menopausal T2DM patients willing to follow SHBPPs were randomly assigned to three different SGLT2-Is (intervention group, IG, $n = 318$) or other drugs (control group, CG, $n = 403$) for 3 months. Before and after treatment, they underwent routine lab tests and completed a specific questionnaire. The present study was carried out by a network of five identically organized outpatient diabetes care units (DCUs) previously documented to attain the same performance levels and to come from a single institution. For the study, we specifically prepared the Female Genital Infection Symptoms Questionnaire (FGISQ) based on GIPR recommendations and checked for appropriate question comprehension and answer concordance as described below by previously administering it to 40 post-menopausal women with T2DM three times at 5-day intervals. Answer concordance was 97%. Based on a specific nurse's inquiry and help request rate by patients completing the test, question comprehension was 98%. FGISQ consisted of sections A and B (Figure 1/A and 1/B). In greater detail, we changed question n.5 from Section A by considering that some women had Figure 1A: Female Genital Infection Symptoms Questionnaire. Part A (FGISQ-A) is addressed to the general prevention recommendations of GIs in women, taken from the recommendations (reference number 28, and Supplementary data, Table S1A, supplementary material), only six of which have been transformed into general questions. Part B (FGISQ-B), investigating GI symptoms and sexual habits is unscored and resumes GIPR questions 5 and 8 (see supplementary material), kept sexually active, and question n.8 to assess the intensity of eventually occurring GI symptoms. We also refrained from formulating any question related to recommendation n.9 as useless (all were post-menopausal, indeed).
RESULTS: GIs more often occurred (9.6%; P < 0.001) among IG women non-adhering to SHBPPs (41.5%) versus the 2.9% of adhering ones. Conversely CG women had superimposable GI rates (2.7% versus 3.1%, respectively, p n.s.) whether or not adhering to SHBPPs (51.4% versus 49.6%, respectively, p n.s.). The typical profile of women on SGLT2-Is at higher risk for GIs included (i) poor adherence to SHBPPs, (ii) older age, (iii) higher BMI, (iv) poor glucose control as witnessed by high HbA1c levels, and (v) antihypertensive drug utilization.
CONCLUSION: Physicians should consider the importance of strict hygiene control in their post-menopausal T2DM patients undergoing SGLT2-I treatment and thus utilize better-focused education strategies in that specific subgroup to prevent or rehabilitate from repeated GIs.

FEMALE GENITAL INFECTION PREVENTION QUESTIONNAIRE Part A (FGISQ-A)

PARTICIPANT NAME (*initials*):_____
ORGANIZATION:_____
Date completed: /__ /__ / /__ /__ / /__ /__ /__ /__ /

The following questions address your treatment regimen and, in particular, your adherence rate to the recommendations on the prevention of vaginal and vulvo-vaginal infections during treatment with an SGLT2-I drug.
Please answer each question by circling a number on each scale or crossing out an answer box.

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1. Did you remember to follow best personal hygiene practice from Recommendations, point 1?

| 0 | | 1 | | 2 | |3 | | 4 |
(never)   (sometimes)   (often)   (quite often)   (consistently)
(0%)   (about 50%)   (80%)   (80 to 100%)   (100%)

2. Did you use undergarments suggested by Recommendations, point 2 ?

| 0 | | 1 | | 2 | |3 | | 4 |
(never)   (sometimes)   (often)   (quite often)   (consistently)
(0%)   (around 50%)   (80%)   (80 to 100%)   (100%)

3. Did you avoid panty liners as suggested by Recommendations, point 3?

| 0 | | 1 | | 2 | |3 | | 4 |
(never)   (sometimes)   (often)   (quite often)   (consistently)
(0%)   (around 50%)   (80%)   (80 to 100%)   (100%)

4. Did you use the underware as suggested by Recommendations, point 4?

(never)   (sometimes)   (often)   (quite often)   (consistently)
(0%)   (around 50%)   (80%)   (80 to 100%)   (100%)

5. Did you adhere to diet as suggested in Recommendations, point 6?

| 0 | | 1 | | 2 | |3 | | 4 |
(never)   (sometimes)   (often)   (quite often)   (consistently)
(0%)   (around 50%)   (80%)   (80 to 100%)   (100%)

6. Did you follow the general hygiene prevention practice suggested by Recommendations, point 7?

| 0 | | 1 | | 2 | |3 | | 4 |
(never)   (sometimes)   (often)   (quite often)   (consistently)
(0%)   (around 50%)   (80%)   (80 to 100%)   (100%)

(Version approved on October 11, 2019 by the Ethics Committee of Campania University "Luigi Vanvitelli", Prot. N. 19/1287).

See text for arbitrarily adopted scoring method.

TABLE 1B. Part B (**FGISQ-B),** investigating genital infection symptoms and sexual habtis, is unscored and resumes RPGIF questions 5 and 8.

FEMALE GENITAL INFECTION SYMPTOMS QUESTIONNAIRE Part B (FGISQ-B)

1. . Have you kept sexually active after menopause onset? (if your answer is no, then skip question n. 2)

NO |__| YES |__|

Abstract