treatment using RigiScan® that besides the frequency-, regi tumescence- (TAU) and rigidity (RAU) of erections at the base and tip of the penis during sleep. As a normal reference, RigiScan® -values from men of similar age and no ED were used. All 70 participants underwent liposuction of 200-360 ml from the abdominal subcutis and ADRCs were isolated using a Cytori Celution® System. Immediately after isolation, the patient received an injection into each corpus cavernosum of 2 ml with either Ringer`s lactate or ADRCs.

RESULTS: The two groups were similar regarding age and comorbidity. Patient-reported outcome measures showed no statistical difference between groups in either the IIEF-5 or EHS scores at baseline, 1, 3, 6, or 12 months. RigiScan® evaluation following method validation and reference setting, showed that for each of the four RAU/TAU parameters, more patients in the treatment group had a response beneficial effect compared to the placebo group with tip TAU being significantly higher (46% vs 11%; p=0.0097). We observed that the probability for improvement in EF remained higher in the treatment group independent of the time between surgery and treatment. No severe adverse events related to the treatment were reported during the follow-up period.

CONCLUSIONS: In conclusion, ADRCs had no measurable effect on IIEF-5 and EHS scores in this study. ADRCs injected into the corpora cavernosum had some effect as evaluated by Rigiscan®, which suggest a potential for ADRC in subgroups of patients despite negative clinical findings in this study.

Source of Funding: Innovation Found Denmark

PD11-10

PHOSPHODIESTERASE-5 INHIBITOR USE AND PROGRESSION TO HEART FAILURE IN MEN WITH CORONARY ARTERY DISEASE AND ERECTILE DYSFUNCTION

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INTRODUCTION AND OBJECTIVE: Coronary artery disease (CAD) and erectile dysfunction (ED) often co-occur due to shared vascular risk factors. Although phosphodiesterase-5-inhibitors (PDE5i) are first line treatments for ED, they have also been shown to improve myocardial perfusion and cardiac contractility. To date, information regarding PDE5i and their perceived cardiac benefits has been limited. We hypothesized that tadalafil, with its high affinity to PDE5 receptors compared with sildenafil, may provide greater clinical benefits in reducing major adverse cardiac events (MACE).

METHODS: A retrospective, propensity-matched cohort study was performed using the TriNetX Research Network. Patients with ICD-10 codes for CAD and ED but not pulmonary hypertension were captured (1/2011-12/2016). Patients were subdivided and analyzed via pairwise fashion according to known prescriptions for tadalafil (T), sildenafil (S), or no treatment (NT). Propensity matching was performed using baseline comorbidities of hypertension, ischemic heart disease, cerebral infarction, diabetes, and hyperlipidemia. Outcomes of interest included 5-year rates of heart failure (HF), acute myocardial infarction (MI), and mortality.

RESULTS: A total of 41,287 male patients were identified, with 6,751 with concurrent tadalafil use, 12,214 with sildenafil use, and 22,321 with NT. When compared with NT, both tadalafil and sildenafil were associated with reduced progression to HF, MI, and overall mortality (Figure 1). Most importantly, compared with sildenafil, tadalafil demonstrated lower progression to HF (HR: 0.85 [0.77-0.94]), MI (HR: 0.86 [0.76-0.97]) and mortality (HR: 0.85 [0.76-0.95]) (Table 1).

CONCLUSIONS: Tadalafil use was associated with a significant reduction in progression to HF, MI, and mortality compared with sildenafil or no treatment. These preliminary results may signal meaningful clinical differences in drug choice for men suffering from CAD and ED, and therefore require further inquiry.

Figure 1 – Kaplan-Meier Survival Curves for Tadalafil, Sildenafil, and No Treatment for Heart Failure, Acute Myocardial Infarction, and Mortality

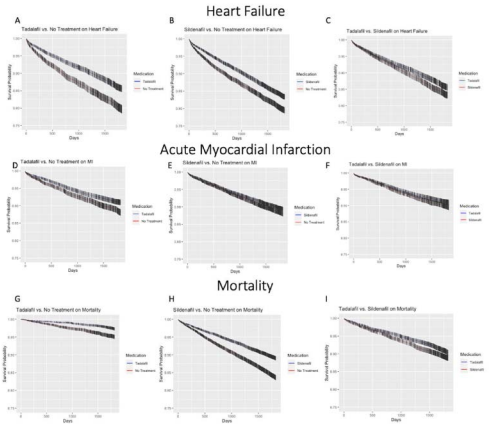

Table 1
Comparison of tadalafil, sildenafil, and no treatment with 5 year cardiac-specific outcomes

	Descriptive@		Propensity-score Matching
Comparison†	N (%)	P-value	HR [95% CI]
5 Year Heart Failure			
Tadalafil vs. No Treatment	711 (12.2) vs. 916 (17.0)	<0.001	0.67 [0.61-0.74]
Sildenafil vs. No Treatment	1,432 (14.5) vs. 1,643 (17.2)	<0.001	0.78 [0.72-0.83]
Tadalafil vs. Sildenafil	711 (12.2) vs. 795 (14.5)	0.002	0.85 [0.77-0.94]
5 Year Acute Myocardial Infarction			
Tadalafil vs. No Treatment	452 (7.7) vs. 553 (9.7)	<0.001	0.75 [0.67-0.85]
Sildenafil vs. No Treatment	935 (9.1) vs. 991 (9.7)	0.005	0.88 [0.80-0.96]
Tadalafil vs. Sildenafil	452 (7.7) vs. 518 (9.0)	0.017	0.86 [0.76-0.97]
5 Year Overall Mortality			
Tadalafil vs. No Treatment	553 (8.2) vs. 895 (13.3)	<0.001	0.59 [0.53-0.65]
Sildenafil vs. No Treatment	1,173 (9.6) vs. 1,687 (13.9)	<0.001	0.65 [0.60-0.70]
Tadalafil vs. Sildenafil	553 (8.2) vs. 664 (9.9)	0.003	0.85 [0.76-0.95]

† Propensity score matched using cardiac-specific comorbidities: Hypertension, Ischemic Heart Disease, Cerebral Infarction, Diabetes, and Hyperlipidemia
@Based on the Log-rank Test

Source of Funding: None

PD11-11

NOVOGLAN FORESKIN TISSUE EXPANDER TREATMENT IS SAFE & EFFECTIVE IN ADULT MALES WITH PHIMOSIS & IT REDUCES PAIN DURING SEXUAL ACTIVITY

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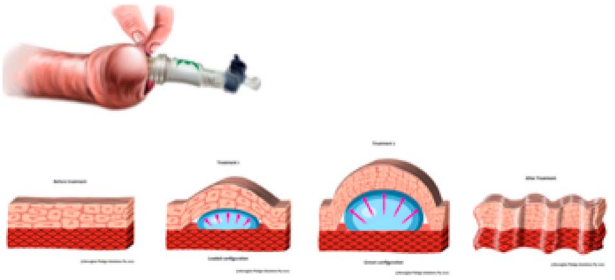
INTRODUCTION AND OBJECTIVE: Men with phimosis can endure pain during sexual activity due to phimosis. This can result in anxiety impacting the patients quality of life. While the mainstay of adult phimosis treatment is circumcision, many men are apprehensive of this intervention due to perceived risk of pain, bleeding, hypersensitivity & reduced sexual pleasure. The Novoglan device stimulates new skin cell growth by applying regular controlled pressure between foreskin & glans allowing it to retract properly. We conducted a clinical trial to establish treatment efficacy, safety & tolerability of the Novoglan foreskin tissue expander & compare patient pain, discomfort & anxiety during sexual activity, pre & post treatment.

METHODS: Analysis of the first 20 cases in the Novoglan-01 clinical trial used ordinal & scalar outcome variables plus descriptive participant variables. Clinical Trial Participation involved two initial visits to a urology clinic, where the patients were consented, trained & their degree of phimosis determined; two phone follow-ups & a final study visit to again determine the degree of phimosis. Phimosis grades were independently assessed by Consultant Urologist on a 1 to 6 scale, where #1 represents absolutely no foreskin retraction & #6 represents full free foreskin retraction. Participant quality of life with phimosis was measured at Visit 1 & again at Final Visit based on general pain / discomfort; pain / discomfort during sexual function, & anxiety.

RESULTS: Efficacy 100% of participants observed full retraction of their foreskin (Phimosis grade 5 or 6) by the final study visit compared with 15% after the first visit. Tolerability 90% reported no pain during treatment. Sexual activity 65% did not experience pain during sexual activity by the final visit vs 5% at the initial visit. 10% experienced

moderate pain during sexual activity by the final visit vs 50% at the initial visit. Anxiety 95% reported reduced level of anxiety post treatment 80% no longer considered circumcision an option post Novoglan treatment

CONCLUSIONS: Novoglan-01 study confirms foreskin tissue expander balloon device is an effective, well tolerated conservative treatment for adult phimosis, enabling quality of life improvement measured by reduced levels of pain, discomfort & anxiety during sexual activity.



Source of Funding: n/a

PD11-12

THE EFFECT OF CLOMIPHENE CITRATE ON PATIENT REPORTED OUTCOME MEASURES

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INTRODUCTION AND OBJECTIVE: Clomiphene Citrate (CC) is a medication that can be used in hypogonadal men in lieu of testosterone to increase testosterone levels while preserving or improving fertility. Patient reported outcome measures for this medication are limited, especially regarding sexual functioning. Our objective is to assess whether self-reported changes in androgen deficiency symptoms and erectile function are observed along with changes in hormone levels and semen parameters in men taking CC.

METHODS: We performed a retrospective review of all patients on CC between 2014 and 2018 for hypogonadism and/or infertility. Patient characteristics including age and body mass index (BMI) along with hormone levels, semen parameters, and self-reported questionnaire scores were obtained. Patients who completed blood work for total testosterone and bioavailable testosterone, a semen analysis, and hypogonadism and erectile function questionnaires including Androgen Deficiency in Aging Male (ADAM) and Sexual Health Inventory for Men (SHIM) before and 3 months after the initiation of CC were included in the analysis. Patients with documented exogenous testosterone, human chorionic gonadotrophin, or anastrozole use were excluded. Changes in baseline and follow-up data were analyzed using paired-sample t-tests.

RESULTS: A total of 97 men were identified and included in the analysis. The mean age and body mass index (BMI) were 33.7 $\pm$ 6 years and 31.2 $\pm$ 7.3 kg/m^2, respectively. All patients were followed for at least 3 months. The use of CC significantly increased both mean total and bioavailable testosterone levels by 236.5 ng/dL and 115.6 ng/dL, respectively ($p<0.05$). Concentration, total progressive motility and morphology all significantly improved as well ($p<0.05$). Clinical manifestations included a significant improvement in ADAM scores ($p=0.025$) and no change in SHIM scores ($p=0.278$).

CONCLUSIONS: As more men are placed on CC for hypogonadism and/or infertility, characterizing patient reported outcomes regarding androgen deficiency symptoms and erectile function are important. The medication is able to raise testosterone levels while increasing semen parameters in addition to improving self-reported hypogonadal symptoms and maintaining erectile function scores.

Labs, Semen Parameters and Questionnaires Pre and Post Clomiphene Citrate (CC)

Labs	Before CC	3 months after CC	P-value
Total testosterone (ng/dL)	322.2 (207.8)	558.7 (271.8)	<0.001
Bioavailable testosterone (ng/dL)	138.9 (66.8)	254.5 (163.3)	0.011
Semen parameters			
Concentration, million/mL	22.3 (44.4)	33.4 (41.9)	<0.001
Morphology, %	1.8 (2)	1.9 (2.2)	0.034
Total progressive motility, %	30.8 (78.4)	48.1 (71.5)	0.001
Questionnaires			
SHIM	22.5 (3.2)	21.6 (4.1)	0.278
ADAM	4.2 (2.2)	2.7 (3)	0.025

Source of Funding: None