1

Holmium laser enucleation of the prostate (HoLEP) vs. Superpulsed Thulium laser (TFL) and Aquablation (Aqua) in men with benign prostatic hyperplasia related obstructive symptoms: A Randomized Clinical Trial.

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Introduction & Objectives: -Background: Bladder outlet obstruction (BOO) affects 1.1 billion men worldwide. Those with moderate to severe symptoms require a surgical intervention. We are living a revolution in surgical treatment, several techniques are available today. However, there is a paucity of comparative effectiveness data between techniques.

-Objectives: We sought to compare the efficacy, impact on quality of life (QoL) of enucleative (HoLEP vs. TFL) and enucleative vs. ablative techniques (HoLEP vs. Aquablation® (Aqua)).

Materials & Methods:

-Design, setting and participants: Between March 2021 and Dec 2022, we conducted a multicenter clinical trial. Patients with moderate to severe BPH obstructive symptoms who elected an enucleation procedure, were assigned to undergo either HoLEP or TFL by a 1:1 randomization. Those who declined randomization or had a prostate volume <120mL. were treated by Aqua or HoLEP as per routine care and followed prospectively.

-Intervention: Randomization HoLEP or TFL.

-Outcome measurements and Statistical analysis: We assessed differences in efficacy, outcomes by improvement from baseline in Qmax (mL/sec), International Prostatic Syndrome Score (IPSS) and QoL-IPSS score) at 6 months. As a secondary endpoint, we compared intraoperative, postoperative complications and sexual function.

Results: Results: 300 patients were enrolled. 200 were randomized to the HoLEP vs. TFL. At 6 months, no difference was detected between HoLEP or TFL in Qmax, IPSS or IPSS-QoL: 29.85±12.52 vs. 29.64±7.98 mL/s (p=0.8), 5.83±4.9 vs. 4.83±4.95 (p=0.57) and 1.62±1.39 vs. 0.67±1.07 (p=0.09); respectively. There were also no differences in complications, hemoglobin drop (HoLEP 0.23±1.03 vs. TFL 0.25±1.0 g/dL; p=0.74). A high anejaculation rate was seen in both arms (HoLEP: 90%, TFL: 87%) (p=0.55).

100 patients enrolled in the HoLEP vs. Aqua arm. At 6 months, there were no differences in Qmax (36.9±25.5 vs. 32.8±10.1 mL/sec, p=0.21), IPSS (4.5±3.6 vs. 2.8±1.4 p=0.47) and IPSS-QoL (0.8±0.6 vs. 1.0±1.2 p=0.10); respectively. Higher postoperative hemoglobin drop was seen in the Aqua group (2.4±1.6 vs. 0.7±1.5 g/dL, p<0.01). The anejaculation rate for HoLEP was (98%) vs. 3 in the Aqua group (6%) (p<0.01).

Conclusions: Conclusions: HoLEP and TFL offer comparable efficacy, and impact on quality of life in the short period time.

Aqua ablation is associated with markedly better preservation of ejaculatory function.

2

Analysis of clinical characteristics in metastatic hormone-sensitive prostate cancer: Bridging the gap between randomized controlled trials and real-world data

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Introduction & Objectives: Androgen deprivation therapy (ADT) was the standard of care (SOC) for patients with metastatic hormone sensitive prostate cancer (mHSPC) for decades; recently, emerging therapies (the so-called ARTA, taxane-based chemotherapy and their combinations) associated with ADT have proven to be more effective than ADT alone, however there is an unmet need of standardization of randomized control trials (RCTs) comparing the various combinations of available drugs. Real Word Data (RWD) may be used to identify relevant outcomes and clinical cohorts with unmet clinical needs with a greater likelihood of benefiting from new therapies. We aim to describe demographics, clinical characteristics, treatment patterns and clinical outcomes of a large multicenter cohort of patients with mHSPC in RWD under the PIONEER project.

Materials & Methods: Data of patients with mHSPC across a distributed network of observational databases were collected. Male patients without prior orchiectomy with mHSPC were enrolled in Cohort 1, defined by those patients with a prostate cancer diagnosis, metastasis diagnosis and exclusion of other malignancies, while Cohort 2 was defined as the start of ADT or other treatment, both in metachronous and synchronous disease settings.

Results: Overall, 94,261 mHSPC patients were included among which 77,123 patients received treatment. 28% of mHSPC diagnosed were not on ADT monotherapy. More than half of the patients were over 70 years old (54%), older than the average age on the available RCT . In cohort 2, 2,819 patients were metachronous and 55,502 patients were synchronous. Most of the patients are treated with ADT only; after a median follow-up (ranged from 398-699 days) in the metachronous setting 22% of them discontinued the treatment. Regarding the clinical outcomes, time to admission to hospital or emergency department, adverse events and death increase with time, but noticeably events are more common in synchronous disease

Conclusions: This is the largest study in Europe using RWD in the mHSPC setting. Landscape of prostate cancer treatment is constantly evolving, so it is important to understand the behavior of the disease in real-world setting, so we are able to fill gaps or create new questions to create evidence. In RWD that patients are older, with more co-mobilities and 1/3 of them do not undergo a SCO treatment when compared to RCT.

3

Prospective evaluation of radical prostatectomy without prior biopsy based on PSA or DRE, mpMRI and PSMA-PET

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Introduction & Objectives: Modern imaging techniques are able to predict advanced prostate cancer with very high level of probability. This raises the question of omitting prostate biopsy as prerequisite for therapy. Here, we present a prospective study of patients undergoing radical prostatectomy (rPx) without prior biopsy, based on DRE, PSA, PSMA-PET and mpMRI.

Materials & Methods: The study was approved by the university clinic ethics committee (#19-693). Inclusion criteria were suspicious DRE or PSA value ≥10 ng/ml, high suspicion of prostate cancer on mpMRI (PI-RADS 4 or 5) and high suspicion of prostate cancer on PSMA-PET imaging. Between 03.19 and 02.23, 27 patients were included into the study (Group 1). After filing for an amendment that allowed to omit one of the two imaging techniques, 8 more patients were included (Group 2). Outside of the study, rPx without prior biopsy was performed in carefully selected cases, who did not meet the inclusion criteria (n = 18, group 3).

Results: Group 1: Median preop PSA was 19.3 ng/ml (interquartile range: 13.9 - 38.9) and PSA density was 0.48 ng/ml/ccm3 (0.3 - 0.6). mpMRI was P4 in 6 and P5 21 patients. In histology, every patient was diagnosed with clinically significant prostate cancer. 7 patients had ISUP grade 2, 10 grade 3, 5 grade 4 and 5 grade 5. The majority of patients showed locally advanced prostate cancer: 1 patient had local tumor stage of pT2a, 9 pT2c, 9 pT3a and 8 pT3b.
Group 2: Median preoperative PSA was 17.4 ng/ml (16.0 - 29.1) and PSAd was 0.29 ng/ml/ccm3 (0.2 - 0.5). mpMRI was P4 in 2 and P5 in 6 patients. In histology, every patient was diagnosed with clinically significant prostate cancer: 1 had ISUP grade 1, 3 grade 2, 1 grade 3, , 1 grade 4 and 2 grade 5. 2/8 patients had local tumor stage of pT2a, 2 pT2c and 4 pT3b. Group 3: All patients had elevated PSA level or abnormal DRE. Median preoperative PSA level was 7.2 ng/ml (5.9 - 8.5) and PSAd was 0.13 ng/ml/ccm3 (0.1 - 0.1). Suspicion of prostate cancer based on abnormal mpMRI in 16/17 patients and abnormal PSMA-PET imaging in 16/16 patients. 14/18 had suspicion of prostate cancer in both modalities. In histology, every patient was diagnosed with prostate cancer: 4/18 patients had ISUP grade 1, 9 grade 2, 4 grade 3 and 1 grade 5. 3/18 patients had local tumor stage of pT2a, 13 pT2c and 2 pT3b.
Group 1 and Group 2 showed a significantly higher rate of locally advanced prostate cancer compared to Group 3 (pT3a or pT3b: 60.6% vs. 11.1%, $p < 0.001$). Group 1 and 2 showed a significantly higher rate of aggressive prostate cancer compared to group 3 (ISUP grade > 2: 66.7% vs. 27,8%, $p < 0.001$).

Conclusions: In this prospective study approved by the Ethics committee, it was shown that radical prostatectomy without prior biopsy can be done finding significant cancer in every single patient. Applying the strict inclusion criteria, histology showed a very high rate of advanced prostate cancer.

4

Survival trend in men with de novo metastatic prostate cancer after the introduction of doublet therapy. Nationwide population-based cohort study

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Introduction & Objectives: In randomized clinical trials, doublet therapy with androgen deprivation therapy (ADT) plus chemotherapy with taxotere or androgen receptor pathway inhibitor drugs (ARPI) increased survival in men with advanced prostate cancer (PCa)
Our objective was to to investigate the introduction of doublet therapy to clincial practise in Sweden and to investigate if there has been any concomitant changes in survival.

Materials & Methods: This is a descriptive non-interventional study in in Prostate Cancer data Base Sweden (PCBaSe) during the time period 2008 to 2020 in a nationwide, population-based cohort study.
Participants were 11382 men were registered with de novo metastatic castration sensitive prostate cancer (mCSPC) in the National Prostate Cancer Register (NPCR) in 2008-2020. NPCR captures >98% of all men with Pca in the Swedish Cancer Registry to which registration is mandated by law.
Exposure was the proportion of men with mCSPC who received doublet therapy assessed by use of data in NPCR, an audit of use of chemotherapy , and of fillings of prescriptions for ARPI in The Prescribed Drug Registry.
Cancer characteristics at date of diagnosis were extracted from NPCR and comorbidity was assessed by use of data in The Patient Registry and The Prescribed Drug Registry.
Main outcomes and measures were standardized overall survival, taking age, comorbidity, and cancer characteristics into consideration estimated by use of a parametric survival model by use of data in The Cause of Death Registry.

Results: There was a shift towards less advanced PCa during the study period with a decrease in median PSA at diagnosis in men with mCSPC from 145 ng/ml (Q1,Q3: 39,571) to 107 ng/ml (Q1,Q3: 27,426).
Upfront treatment with doublet therapy in men with mCSPC increased from 1% in 2016 to 44% in 2020.
The adjusted 5-year overall survival increased from 26% (95% CI: 25-28%) in 2008-2012 to 35% (95% CI: 31-40%) in 2017-2020. During the first 5 years after diagnosis there was an increase in mean survival of 6 months, from 2.7 years (95% CI: 2.6-2.8) in 2008-2012, to 3.2 years (95% CI: 3.1-3.1) in 2017-2020.

Conclusions: In parallel with improvements in treatment of advanced prostate cancer, a clinically meaningful increase in mean survival was observed in men with de novo mCSPC in Sweden between 2008 and 2020. In parallell a continued decrease in tumour burden was observed
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5

How can we be more PRECISE? Reporting MRI in men on active surveillance for prostate cancer

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Introduction & Objectives: MRI is an important tool in men on active surveillance for localised prostate cancer. The PRECISE guidelines were developed in 2017 for the reporting of serial MRI in men on active surveillance, both for an individual patient and for reporting studies in these cohorts. Like all guidelines, a review and refresh is warranted after some use, and an international consensus group met in September 2023 to discuss revisions and additions to the current PRECISE approach.

Materials & Methods: Formal consensus methodology using a modified RAND-UCLA approach was used. A panel of statements was developed and international experts across radiology (n=20), urology (n=16) and oncology (n=1) were invited to score their agreement with the statements on a 1 to 9 scale. These results were collated and presented to panellists for discussion at 6 hours of live video conferencing. Statements could be added, revised or removed during discussion. Each panellist then rescored each statement independently. These repsonses were analysed and noted as disagreement, uncertainty or agreement based on the median score (1-3, 4-6, 7-9), with a measure of consensus or no consensus derived from the distribution of scores around the median.

Results: It was agreed that unless the scan meets a minimum image quality standard, using an approach such as PIQUAL, it should not be used to assess active surveillance eligibility. A minimum of one year should be left between follow up scans. Whenever possible, the lesion should be measured on T2-weighted imaging, using other sequences to aid identification of the lesion if it is more conspicuous on those sequences. It is important to report the lesions pictorially using either a diagram, key images as screenshots or a contour on axial T2-weighted images.
The current PRECISE score (1-to-5 scale) was modified so that PRECISE 3 (stable MRI) is sub-divided into 3V for visible disease and 3 NonV for non-visible disease.
It was agreed that more research needs to be done on what a significant size change on MRI for men on active surveillance is. It was discussed that smaller lesions will have a higher % increase in volume, but may still be at a size suitable for surveillance, and that defining a threshold for both a significant size of lesion, and for significant change in size would be helpful. There was no agreement , after significant debate, about the use of two axes vs volume by planimetry or whether a doubling time concept should be adopted.

Conclusions: The PRECISE v2 score was modified so that PRECISE 3 (stable) is sub-divided into 3V for visible disease and 3 NonV for non-visible disease. More research needs to be done on what a significant size change on MRI for men on active surveillance is.

6

“Histofusion” biopsy of the prostate: Analysis of multicenter national data in real-life settings

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Introduction & Objectives: Fusion biopsy of the prostate is widely used worldwide to diagnose prostate cancer (PCa). MRI-fusion is the preferred method, although other imaging modalities are used in many centers for biopsy targeting, as systems for MRI-guided fusion are not easily available everywhere and the access to proper MRI evaluation by expert radiologist is often limited. The aim of our study was to analyze the prospectively collected database of Prostate HistoScanning-Guided biopsies (PHS-Bx=Histofusion biopsy) in real life settings.

Materials & Methods: The equipment for Histofusion biopsy of the prostate has been installed in 10 large City Hospitals / Departments of Urology in 2019 – in order to facilitate the biopsy pathway for both urologists and patients. Teams have been trained to perform PHS-Bx properly and uniformly. The PHS-Bx technique has been re-assessed and modified accordingly after 1 and 3 months in all centers by 3 experts. All data has been prospectively collected in a web-based registry and subsequently analyzed. From 2019 to 2023 Histofusion biopsies were performed transrectally under local anesthesia in an outpatient setting in 5 638 patients. The present analysis included 4 946 men from 42 to 85 y.o. with total PSA 2-2020 ng/ml with at least one PHS-detected lesion >0.5 cc.

Results: The median patient age was 66 yr., total PSA 7.8 ng/ml, prostate volume 48 cc, family history of PCa in 1.8% and presence of palpable nodules in 35.8% of cases. The median number of targeted cores was 4, random cores 12. PCa was detected in 49% of cases (Grade group 1 – 49.7%, 2 – 23.7%, 3 – 10%, 4 – 10.6%, 5 – 6%). Age ≥69 yr. (OR 1.72), prostate volume <48 cc (OR 3.15), positive DRE (OR 2.29), presence of ≥2 lesions >0.5 cc (OR 1.92), volume of local anesthetic injected (<20 vs >20 cc) and patient position (left side vs lithotomy) were significant risk factors for PCa detection. Combined biopsy technique (PHS-guided + systematic) detected the largest amount of PCa cases (68.2%) comparing to only random or targeted cores. GG ≥2 was present in 40.9% of cases diagnosed with combined approach. The Clavien-Dindo complication rate was law with no significant difference between groups. The study has many limitations including non-randomized character, suboptimal sensitivity and specificity of PHS, inter-observer variability, absence of direct comparison with MRI-fusion biopsy etc.

Conclusions: MRI-guided prostate biopsy is slowly replacing systematic biopsy, although the use of pre-biopsy MRI is not affordable in many health care systems. The analysis of a large prospectively collected Big Data has demonstrated, that PHS-guided biopsy provided high detection rate of clinically significant PCa with low rate of complication and lower price (data not presented). Uniform way of biopsy performing and centralized data collection allowed to identify PCa predictors and optimize prostate biopsy technique in real life settings.

7

Molecular features of clinical outcomes in men with localized intermediate-risk prostate cancer treated with pre-operative apalutamide

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Introduction & Objectives: A subset of men with localized intermediate-risk prostate cancer (LIRPC) who undergo radical prostatectomy (RP) are found to have pathologic upstaging, and given the high incidence of LIRPC, these men comprise a meaningful cohort of those who develop recurrent disease. Androgen signaling inhibition without the use of testosterone suppressive therapy is a potential strategy to reduce the number of men with LIRPC who develop recurrent, potentially lethal disease following primary treatment. We evaluated molecular alterations associated with clinical outcomes in a cohort of men who received 6 months of pre-operative apalutamide prior to RP.

Materials & Methods: RP specimens were obtained after 6 months of pre-operative apalutamide on a single institution, phase II clinical trial between May 2018 and February 2020 (NCT03412396). Correlative studies, including DNA sequencing, transcriptomic profiling, and selected protein stains, were evaluated on RP specimens for association with clinical outcomes of interest, including high-risk surgical pathology (pT3 or N1 or positive surgical margins) and biochemical recurrence (BCR) at 3-years. For transcriptomic studies, Hallmark GSEA was supervised by these clinical endpoints. Additionally, a Hallmark GSEA of untreated Gleason 7 tumors from TCGA was supervised by pT3 verse pT2 to help understand whether our findings are driven by treatment or T stage.

Results: 40 patients had RP specimens available for bulk RNA sequencing and immunohistochemistry (IHC) staining. The RP specimen was exhausted for 1 patient prior to somatic DNA whole-exome sequencing (WES), and all 40 patients had germline DNA WES performed on blood control. Genomic alterations commonly found in metastatic prostate cancer were not prevalent in this cohort. High-risk surgical pathology (n=16/40) and BCR at 3-years (n=6/30) were associated with increased expression of select cell cycle and oxidative phosphorylation (OXPHOS) pathways (Padj < 0.001). In the GSEA of Gleason 7 tumors from TCGA (n=246), pT3 tumors were associated with a similar upregulation of select cell cycle and OXPHOS pathways (Padj < 0.001).

Conclusions: From a trial of pre-operative apalutamide for LIRPC, correlative analyses identified key pathways including cell cycle and OXPHOS upregulated in patient tumors with adverse pathologic outcomes and higher risk of disease recurrence. Future studies to develop prognostic and predictive biomarkers in order to further understand and target these errant pathways are warranted.

8

The JUPITER registry: A European registry to address on focal therapy for prostate cancer in the real-world

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Introduction & Objectives: In recent years, there has been a rapid increase in clinical data regarding Focal Therapy (FT) for localized PCa, and the guidelines now recommend FT for intermediate-risk PCa patients participating in prospective registries and/or clinical trials. The main criticism of FT is the lack of high-quality oncological evidence. To address the limitation of data from single-center and/or retrospective studies, the EAU Focal Therapy Board collaborated with the EAU-Research Foundation (EAU-RF) to establish a prospective and multicenter registry, named JUPITER.

Materials & Methods: JUPITER registry aims to recruit 1,000 patients from expert European centers (each center treating a minimum of 20 patients yearly). Eligible patients' criteria are: men with a life expectancy of over 10 years diagnosed with an intermediate-risk PCa or patients with low-risk PCa for whom the FT is considered as an alternative to active surveillance (AS), refused or discontinued; patients underwent primary focal treatment (target or partial gland ablation) on lesions defined on mpMRI, in which a previous targeted + systematic biopsy using MRI fusion-targeted technique have been found a ISUP ≤3 within areas of treatment (ISUP 1 outside the areas of treatment is acceptable, independently of volume). The primary outcome is to collect oncological data (Failure-free survival, Metastasis-free survival, Overall survival) up to 60 months following treatment. Failure is defined as an ISUP ≥2 prostate cancer in the treated area during follow-up or the necessity of any additional active treatment for PCa management (excluding AS or a new focal treatments). The primary outcomes also encompass the type of salvage treatments and their associated complications. Secondary aims are analyzing treatment-related safety (number and grading according to Clavien-Dindo of FT related-complications) and its functional impact (QoL, urinary, erectile and ejaculatory functions).

Results: Currently, 27 centers from 10 European countries have expressed their willingness to participate. Following a protocol review by the EAU Focal Therapy Board, the panel has compiled a list of potential 'country coordinators', also referred to as Ambassadors, who will aid each center in their respective countries in enrolling patients in the registry through on-site visits, simplifying the process of data collection, management, and updates on the online platform. EAU RF, using Castor Data Management Platform, has developed the initial database, ready for the first revision in November 2023. Language packages, including the electronic Case Report Form (eCRF), functional and quality-of-life questionnaires, registry protocol, and consensus form, are also in the development phase.

Conclusions: The JUPITER registry could potentially provide the long-awaited evidence for Focal Therapy that many clinicians involved in PCa care have been eagerly anticipating.

9

Focal therapy with High-Intensity Focused Ultrasound (HIFU) for the treatment of prostate cancer: Three year outcomes from a prospective trial

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Introduction & Objectives: High-quality data on the outcomes of focal high intensity focused ultrasound (HIFU) for the treatment of prostate cancer remains limited. We present the 3-year results of a prospective clinical study designed to assess the oncologic and functional outcomes of this procedure. Unique to our study, we performed periodic protocol-mandated post-ablation saturation biopsies to document failure-free survival among treated patients.

Materials & Methods: Men with two or less lesions of grade group 3 prostate cancer were eligible for participation in this single center prospective study of highly targeted, or 'focal', HIFU. Additional inclusion criteria included a PSA of ≤15 ng/mL, clinical stage cT1c-T2, and a life expectancy of ≥10 years. The primary study endpoint was failure-free survival (FFS), defined as absence of any clinically significant PCa (csPCa) in-field or out-of-field on protocol-mandated saturation biopsy, and no whole-gland or systemic salvage treatment, PCa metastasis, or PCa related death. Results are reported using two distinct definitions of csPCa: (1) the presence of any grade group ≥2 PCa and (2) any grade group ≥3 or a cancer core length involvement of ≥ 6 mm at any location. Secondary endpoints were functional outcome evaluated by several established questionnaires addressing urinary, sexual, and bowel function.

Results: Ninety-one patients were included in the study, including 6 (7%) patients with grade group 1 PCa and 85 (93%) with grade group 2 or higher disease. A total of 83 (91%) patients underwent at least 1 follow-up biopsy. Biopsy attendance at 6, 12, and 36 months was 84%, 67%, and 51%, respectively. FFS at these timepoints for any grade group ≥ 2 PCa was 79% (95% CI 80-88%), 57% (95% CI 48-69%) and 44% (95% CI 34-56%), respectively. Using the second definition, the rates of FFS were 88% (95% CI 81-95%), 70% (95% CI 61-81%) and 65% (95% CI 55-77%), respectively. 3-year cancer-specific survival was 100%, and freedom from metastasis was 99%. mpMRI (7.7% sensitivity, 95% CI 0.2-36%) and PSA nadir values over time (p = 0.4) performed poorly to detect disease recurrence. Urinary symptoms and bowel assessment returned to baseline questionnaire scores within 3 months. 16 (21%) patients experienced meaningful worsening in erectile function. A significant decrease of PCa related anxiety was observed.

Conclusions: Focal HIFU treatment for localized prostate cancer shows excellent functional outcomes with adequate prostate cancer control in the mid-term. Radical treatment was avoided in 81% of patient. Early follow biopsies are crucial to change or continue the form of therapy at the right time, while the use of MRI and PSA in detecting PCa recurrence is uncertain.

10

A prospective cohort study evaluating mental wellbeing in Prostate Cancer: The MIND-P Study

European Urology Open Science 2024;60 (Supplement 1): S10

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Introduction & Objectives: There is increasing evidence to demonstrate the profound impact on mental wellbeing a diagnosis of prostate cancer can have. This "mind and body" study aimed to investigate the patient, treatment, and oncological prognostic factors for multiple mental wellbeing outcomes in prostate cancer.

Materials & Methods: MIND-P is a prospective multi-institutional cohort study across 8 UK sites (NCT04647474) evaluating mental health in newly diagnosed prostate cancer patients, followed up for 12 months since diagnosis, with 3-monthly questionnaires evaluating mental, physical, and social wellbeing. Five mental wellbeing outcomes of interest (depression, anxiety, fear of recurrence, body image or masculine self-esteem) were selected based on extensive background literature searches. Cumulative incidence of significant wellbeing issues was calculated with multivariate regression utilised to explore baseline patient, oncological and treatment factors against each individual outcome. Subsequently, a multivariable prognostic model was developed.

Results: 300 newly diagnosed prostate cancer patients were recruited. In these 13.7% and 11% developed significant depression or anxiety. Overall, 45% developed at least one mental wellbeing issue. Those undergoing hormone monotherapy had poorer body image (aOR 3.88, p=0.04). Metastasis at diagnosis was associated with increased depression (aOR 4.09 p=0.01), anxiety (aOR 3.58, p=0.03) and fear of recurrence (aOR 2.98, p=0.01). Younger age at diagnosis, a previous mental health history, baseline mental health symptoms and poorer baseline urinary and sexual function led to poorer mental well being.
A multivariable model was developed based on age, previous psychiatric diagnosis, stage, baseline anxiety, and baseline urinary and sexual function. The developed model demonstrated acceptable overall performance, calibration and discrimination during internal validation.

Conclusions: The MIND-P study has confirmed that mental health problems are common in prostate cancer, demonstrating the importance of these outcomes in prostate cancer care. Patient predictive features including younger age, advanced disease, baseline wellbeing and functional status should be considered to ensure that patients at higher risk are monitored during routine follow up so that mental health issues can be identified and treated earlier.

11 Changing clinical study design using platform trial methodology: The STAMPEDE Trial 20 years on

European Urology Open Science 2024;60 (Supplement 1): S11

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Materials & Methods: A platform trial is an adaptive RCT, whereby an established "standard of care" in a particular disease area (the "control") is tested against other alternative clinical interventions to establish whether improvements can be made to the established "standard". The STAMPEDE trial in prostate cancer was the first ever large-scale platform trial and it is the longest running (www.thestampedetrial.org). Conceived and designed between 2003 and 2004 it was launched in 2005. In 2019 it was voted "world's best cancer trial" by the Society of Clinical Trials. This landmark study set a future course for the development and prosecution of platform trials not only in oncology but in multiple specialty areas of medicine, such as the Recovery Trial for COVID-19. STAMPEDE's “multi-arm” comparison was defined clearly right at the start, as was the “multi-stage” element, requiring early stopping rules for toxicity, ability, to recruit, lack of efficacy etc. Thus, early rejection of ineffective or toxic agents was possible, enabling new arms to be started rapidly with an unchanged control. This novel ability to “switch arms” shortened new trial recruitment times by @ 4 years, which, added to the foreshortening of time to trial end-point reporting (from 15 to 10 years) engendered the ability to answer multiple questions synchronously and in a much shorter time. Analysis of STAMPEDE's trial data was predicated on its statistical power relative to defined endpoints and statistical analysis plans were pre-defined for specific parameters. This accommodated novel endpoints and control-arm changes during the period of specific trial arms, exemplified by the establishment of metastasis-free survival as a defined outcome. Using this methodology STAMPEDE has randomised >11,000 patients from 2015 onwards, helping to change trial design and international practice repeatedly in Hormone Sensitive Prostate Cancer. Parallel translational research programmes have been developed in STAMPEDE, thinking creatively about data curation, imaging and biological sample collection/storage, linking this with basic and translational science, epidemiology etc, studying genomics, imaging, health-economics and AI linked to treatment and outcome. Trial data is also cross-referenced with large-scale “real world” population-based information, enabling better therapeutic targeting and reduced treatment toxicity, including incorporation of data in international meta-analyses through the ICECaP and STOPCaP initiatives. Future-proofing of platform trials is critical because of their longevity. STAMPEDE has modified its methodologies and recruited new trialists and researchers, adapting to a new clinical, therapeutic and regulatory climate in the design of STAMPEDE 2, so that the next 15-year platform trial programme may continue to build on the 20 year success of STAMPEDE 1, the pioneer platform trial.

12

The importance of being grade 3 in primary non-muscle invasive bladder cancer

European Urology Open Science 2024;60 (Supplement 1): S12

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Introduction & Objectives: Histological grade of non-muscle invasive bladder cancer is an important predictor of progression. Although the WHO2004/2016 system is recommended, other classification systems like WHO1973 and WHO1999 are still widely used. Recently, a Hybrid (three-tier) system was proposed, which separates the WHO2004/2016 high-grade (HG) category into HG/G2 and HG/G3 while maintaining low-grade (LG). We examined the prognostic value of HG/G3 compared to HG/G2.

Materials & Methods: Three independent cohorts with a total number of 9,712 primary (first diagnosis) Ta-T1 bladder tumors were analyzed. Time to progression was analyzed with cumulative incidence functions and Cox-regression models. Harrell's concordance (C) index was used to assess the prognostic accuracy of the models.

Results: Time to progression was significantly shorter for HG/G3 compared to HG/G2 in multivariable analyses (Cohort1: HR1.92, P<0.001; Cohort2: HR2.51, P<0.001 and Cohort3: HR1.69, P=0.024). Risk of progression at 5-years was 7.3%, 7.5% and 9.3% for HG/G2 versus 18%, 20% and 18% for HG/G3 in the 3 cohorts, respectively. In all 3 cohorts, Cox models using Hybrid grade performed significantly better than the models with WHO2004/2016 (all; P<0.001). In the 3 cohorts, Harrell's C-indices for WHO2004/2016 were 0.69, 0.62 and 0.75, respectively; Harrell's C-indices for Hybrid grade were 0.74, 0.68 and 0.78, respectively.

Conclusions: Prognostic accuracy of the (three-tier) Hybrid classification system to assess grade was better than the WHO2004/2016 system. A group of HG-patients with worse prognosis can be identified by G3. Based on the present study, subdividing the HG-category into HG/G2 and HG/G3 is recommended.

13

Establishment and application of patient-derived organoids as a functional system to assess therapy response in bladder cancer

European Urology Open Science 2024;60 (Supplement 1): S13

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Introduction & Objectives: Bladder cancer (BLCa) interpatient heterogeneity is one of the causes of therapy failure suggesting that patients would benefit from tailored therapies. Patient-derived organoids (PDOs) have been used for functional assays for predicting drug response in distinct cancers.
In this study, we generated BLCa PDOs and assessed their drug response and similarity with the primary tissue (PT). We associated PDO drug responses with their genomic and patient's outcome.

Materials & Methods: Organoids were derived from the suspension culture of single cells. Genomic DNA was used for whole exome sequencing and scRNA sequencing was performed on 3 PT/PDO pairs. Histological evaluation of PDOs and PT morphology was performed. PDOs were treated for 48h and their viability was measured.

Results: PDOs were generated from non-muscle invasive and muscle invasive BLCa. According to the genomic characterization, the copy number variations and single nucleotide variants (SNVs) of 15 PT/PDO pairs were well matched. PDOs conserved significant BLCa alterations, and the PT heterogeneity as observed by the agreement between the SNV clonality profiles. PDOs preserved PT phenotype as shown by marker analysis, and presented several morphologies associated with markers and the PT stage.
PDOs used in drug screening assays to evaluate FDA-approved and standard-of-care drugs showed mixed responses likely due to interpatient diversity. In 1 case, PDO response matched patient's prognosis, and in a few other cases, sensitivity was linked to mutations.
We performed 2 longitudinal studies do the high BLCa relapse rate. The first study includes 2 lesions collected before (baseline) and after (relapse) epirubicin. Relapse PDOs had higher mean SNV clonality and were less susceptible to epirubicin than baseline PDOs which contained mutations in DNA damage repair genes. Therefore, we hypothesize the selection of a pre-existing epirubicin-resistant population between the 2 samples. The second study instead, includes a cystectomy and a relapse in the upper urinary tract. PDOs from both samples had similar genetic and drug response profiles indicating that the first sample may be informative for adjuvant therapy.

Conclusions: We generate PDOs from several BLCa stages and grades that preserved PT features. We presented the utilization of PDOs in drug screening assays and we emphasized their role in precision medicine with the longitudinal studies showing the ability of PDOs to replicate patient response and tumor progression in vitro.

14 Cystectomy for bladder cancer – have outcomes improved after centralization?

European Urology Open Science 2024;60 (Supplement 1): S14

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Introduction & Objectives: Radical cystectomy (RC) for bladder cancer is a complex procedure with an inherent risk of complications and even postoperative mortality. Historically, RC was performed in 44 hospitals in Sweden, which gradually decreased over time, and since a formal regional centralization in 2017, cystectomy-care is currently provided by nine hospitals.

Materials & Methods: In the Swedish National Urinary Bladder Cancer Register (SNRUBC) 90-day complications after RC have been registered with high coverage since 2012, with data presented in an interactive and open online data resource (RODRET). These aggregated data were utilized to compare outcomes in relation to centralization of the cystectomy-care by stratifying outcomes before (2012-2016) and after (2017-2022).

Results: Out of all 4309 cystectomies, 2411/4309 (56%) were performed after the centralization in 2017 and onwards. The median age at RC increased from 69 (IQR 64-75) to 73 (IQR 67-78) years, and the proportion of patients with comorbidity (ASA 3 or 4) increased from 33% to 41% after the centralization. The number of patients suffering from high-grade Clavien 3, 4 or 5 complications within 90 days of surgery were 344 (18%), 61 (3%), and 33 (2%) before 2017, and 369 (15%), 59 (2%), and 22 (1%) after centralization, respectively. A continuous decline in 90-day mortality from 19/273 (7%) in 2012 to 8/395 (2%) in 2022 and reoperations within 90-days of RC from 36/273 (13%) in 2012 to 27/395 (7%) in 2022 were also observed.

Conclusions: It is likely that the centralization of the cystectomy-care in Sweden has contributed to improved outcomes after RC.

15

Long-term results from the randomized trial LEA: Extended Versus Standard Lymph Node Dissection in Bladder Cancer Patients Undergoing Radical Cystectomy

European Urology Open Science 2024;60 (Supplement 1): S15

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Introduction & Objectives: The extent of lymph node dissection (LND) in bladder cancer (BCa) patients at the time of radical cystectomy may affect oncologic outcome. Here we present long-term data of a prospective, multicenter, phase-III trial including patients with locally resectable T1G3 or muscle-invasive urothelial BCa (T2-T4aM0), which was initially published in 2019 (Gschwend et al. Eur Urol).

Materials & Methods: The primary endpoint was time to progression (TTP). Secondary survival endpoints included cancer-specific survival (CSS), overall survival (OS). The trial was designed to show 15% advantage of 5-yr RFS by extended LND. Patients were randomized to standard (obturator, and internal and external iliac nodes) versus extended LND (in addition, deep obturator, common iliac, presacral, paracaval, interaortocaval, and para-aortal nodes up to the inferior mesenteric artery).

Results: Results: In total, 401 patients were randomized from February 2006 to August 2010
(203 limited, 198 extended). The median number of dissected nodes was 19 in the standard and 31 in the extended arm.
Median follow-up of patients being alive without disease recurrence was 58.4 mo. At the time of analysis, tumor recurrence was observed in 123 (30%) patients (68 [33%] in the standard vs 55 [28%] in the extended LND group). A total of 195 (49%) patients deceased (105 [52%] in the standard vs 90 [45%] in the extended LND group), including 100 (25%) patients who died of BCa (60 [30%] in the standard vs 40 [20%] in the extended LND group).
Extended LND failed to show superiority over standard LND with regard to TTP (5-yr TTP 68% vs 60%; hazard ratio [HR] = 0.80 [95% confidence interval 0.56–1.14]; p = 0.23) and OS (5-yr OS 57% vs 51%; HR = 0.84 65 [95% confidence interval 0.64–1.12]; p = 0.24), while CSS was significantly longer in the extended LND arm (5-yr CSS 76% vs 65%; HR = 0.65 [95% confidence interval 0.43–0.96]; p = 0.03).

Conclusions: Extended LND failed to show a significant advantage over standard LND in TTP and OS, while CSS was significantly longer with longer follow-up (ClinicalTrials.gov NCT01215071).

16

Renal tumor heterogeneity in sporadic and inherited renal cancer: a translational multimodal approach

European Urology Open Science 2024;60 (Supplement 1): S16

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Introduction & Objectives: Patients with sporadic or hereditary clear cell renal cell carcinoma (ccRCC) show high intra tumor heterogeneity. Moreover, metabolic, angiogenic, immune or inflammation gene signatures define tumor subtypes with different outcomes and response to therapy. Also, it is currently unknown if a preoperative biopsy and radiomics, along with basic research data, can inform clinical decisions at the time of diagnosis.

Materials & Methods: To comprehensively map intra and intertumoral heterogeneity of ccRCC, we approached two cases of ccRCC (one sporadic and one inherited in the context of VHL syndrome) with a systematic multimodal methodology consisting in: 1) pre-surgery imaging using multiparametric MRI; 2) multi-region ex-vivo biopsies of the surgical specimen for single cell RNA sequencing and somatic mutations analysis; 3) multiplex immunohistochemistry and 4) ccRCC-derived tumor organoids (PDO).

Results: Prior to surgery, renal tumors of both the sporadic and inherited cases were characterized by a multiparametric MRI study including Diffusion Weighted Imaging with Apparent Diffusion Coefficient maps for the characterization of cellularity and dynamic contrast enhancement study using 3D sequence for the quantitative characterization of tumor microperfusion. Renal lesions were automatically extracted on T2w images, and coregistered on T2, ADC and k trans map for the extraction of information about edema, cellularity and perfusion.
Regarding the inherited (VHL) case, 5 lesions were included in the multimodal analysis. Tumors size ranged from 5-55 mm. At final pathology, all the lesions resulted ccRCC. The three smallest tumors (5, 9 and 20 mm) were pT1a low grade, the 55 mm tumor resulted pT3a G2 and the 30 mm tumor was staged as pT1a G3. Most of the tumors (n=4) were VHL mono driver and 1 tumor was VHL BAP1 mutated. All the tumors showed high chromosomal instability, with 3p loss and 5q gain and a high percentage of 14q loss. There was heterogeneity in the cell type distribution. There were pro-inflammatory and pro-tumoral macrophages distributed equally in all the tumors. The lesions shared 22 up-regulated genes. HIF-2 alpha targets were highly expressed in all the tumoral lesions relative to the normal parenchyma. There was heterogeneity at the level of immune response, metabolism and stress in the cancer cells. Regarding scRNAseq analysis, integrative analysis showed different cell clusters identified as epithelial-cancer, immune and stromal cells clusters. The lesions were different in terms of tumor microenvironment (TME) composition, as well.

Conclusions: We set and characterized a multimodal systematic approach to analyze intratumoral and intertumoral heterogeneity in sporadic and inherited ccRCC, with respect to clinical phenotype, TME composition and gene expression.

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Birt-Hogg-Dubé syndrome: Clinical and genetic observations in the Dutch centre of expertise

European Urology Open Science 2024;60 (Supplement 1): S17

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Introduction & Objectives: Birt-Hogg-Dubé syndrome (BHD) is an autosomal dominant condition affecting skin, lungs and kidneys, caused by pathogenic variants in the FLCN gene. Earlier reports suggested a potential increased risk of colorectal cancer in BHD, however this association remains unclear. Here we provide an update on clinical and genetic observations in our cohort.

Materials & Methods: 1. We evaluated renal surveillance compliance and outcomes in 199 patients. 2. We examined available data on colorectal neoplasms in BHD patients and their unaffected relatives. 3. We performed extensive clinical and genetic analysis in two families with an inherited BHD-like phenotype without an identifiable variant in FLCN.

Results: Ad 1. Compliance to recommended renal surveillance was high. Of patients known to be under surveillance, 83% was screened annually and 94% at least bi-annually. Ad 2. No evidence for an increased prevalence of colorectal carcinoma (CRC) was observed in our cohort. Ad 3. Two families with suspected BHD but without an FLCN variant were studied in detail. The first family presented with autosomal dominant trichodiscomas. The phenotype was linked to a locus on chromosome 5 including a predicted truncating variant in FNIP1. In the second family, multiple family members had fibrofolliculomas, lipomas and renal cell carcinoma. A heterozygous missense variant in PRDM10 (p.Cys677Tyr) was found, which directs FLCN expression in a novel disorder overlapping with BHD and familial lipomatosis.

Conclusions: Compliance to renal surveillance in BHD patients was comparable to that in Lynch syndrome, no tumours >3 cm were missed using yearly ultrasound alone. In our cohort we observed no significant differences in CRC number or age at diagnosis in BHD vs controls. No evidence was provided for an increased risk for CRC in BHD syndrome. A locus on chromosome 5 including a frameshift variant in the FNIP1 gene was shown to be shared in 9 families with familial multiple discoid fibromas. We identified PRDM10 as a regulator of FLCN in a family associated with RCC, lipomatosis and skin lesions.

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Off-clamp sutureless robot-assisted partial nephrectomy for high-complexity renal tumours: an exploratory study

European Urology Open Science 2024;60 (Supplement 1): S18

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Introduction & Objectives: During robot-assisted partial nephrectomy (RAPN), both ischemia and renorrhaphy might significantly affect short- and long-term renal function, the latter also potentially inducing predisposing bleeding conditions, such as pseudoaneurysms and arteriovenous fistulas. We evaluated the feasibility and perioperative outcomes of an off-clamp sutureless technique in patients with high-complexity renal tumours undergoing RAPN.

Materials & Methods: A prospectively maintained two-centre RAPN database was queried for patients with high-complexity renal tumours, defined as those with a Preoperative Aspects and Dimensions Used for an Anatomical classification score ≥10, scheduled to undergo off-clamp sutureless RAPN between January 2022 and September 2023. All procedures were performed by expert surgeons using the da Vinci® X or Xi platform. Renal hilum was isolated and renal artery was suspended. RAPN consisted of a simple enucleation using an incremental haemostasis with bipolar fenestrated forceps and monopolar curved scissors with neither ischemia nor renorrhaphy. Haemostatic agents (Hemopatch® or Floseal®) were placed on the enucleation bed. Outcome measures were: 1) success rate of the procedure, 2) operating room time, estimated blood loss, intraoperative complications, positive surgical margins rate, and 90-day postoperative complications and renal function change from baseline (measured with estimated glomerular filtration rate) for successful procedures.

Results: Median age was 65 (interquartile range [IQR] 60-69) years. All patients had a contralateral healthy kidney. Off-clamp sutureless RAPN was successfully performed in 20/28 (71%) patients with high-complexity renal tumours. Reasons for failure in the 8 patients were: arterial clamping (n=2), renorrhaphy (n=5) and nephrectomy (n=1). In successfully completed procedures, median operating room time was 112 (IQR 82-135) min, and median estimated blood loss was 140 (IQR 100-210) ml. No intraoperative complications were observed. Positive surgical margins were observed in 1/20 (5%) cases. Ninety-day postoperative complications were minor (grade 2) in 3/20 (15%) patients. No major complication was recorded. Median baseline and 90-day estimated glomerular filtration rate were comparable (86.9 [IQR 64.9-105] ml/min vs 87.2 [IQR 77.6-104.6] ml/min, respectively; p=0.66).

Conclusions: RAPN with off-clamp sutureless technique with incremental haemostasis is a feasible option for the majority of high-complexity renal tumours, and is associated with low morbidity and good early renal function. Adequately powered, prospective, and comparative studies are required to further investigate the role of this technique.

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Limited utility of quantitative thresholds on 99mTc-sestamibi SPECT/CT for distinguishing renal cell carcinoma from oncocytic renal masses

European Urology Open Science 2024;60 (Supplement 1): S19

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Introduction & Objectives: Assessing renal masses non-invasively remains challenging with about 15% proving benign upon resection. Standard imaging struggles to differentiate low-risk oncocytomas and hybrid oncocytoma/chromophobe tumors (HOCTs) from malignant lesions. Technetium-99m-sestamibi SPECT/CT, a nuclear imaging modality targeting mitochondria, showed promise. However, 20% of lesions with low 99mTc-sestamibi uptake were oncocytomas. This study uses quantitative thresholds to potentially enhance the test's accuracy.

Materials & Methods: From February 2020 to December 2021, renal mass patients undergoing 99mTc-sestamibi SPECT/CT were analyzed. Masses were labeled “hot” if their 99mTc-sestamibi uptake was equivalent or higher than the ipsilateral renal parenchyma, otherwise “cold”. Using software, TBRs were calculated by comparing mass signals to normal renal parenchyma. These determinations were re-evaluated using TBR cutoffs of 0.46 and 0.6. Qualitative and quantitative findings were correlated to histology.

Results: 78 patients underwent 99mTc-sestamibi SPECT/CT for 98 renal masses. 52 masses had diagnostic pathology available from either renal mass biopsy or surgical excision (2 non-diagnostic biopsies were excluded). Of these, 7 were “hot” (1 RCC, 6 oncocytomas) and 45 were “cold” (34 RCC, 2 non-RCC malignancies, 9 oncocytomas). The negative predictive value of qualitatively-interpreted “cold” 99mTc-sestamibi SPECT/CT for ruling out oncocytoma was 80%. 1/52 (1.9%) of malignant masses were interpreted as “hot” and thus likely benign. When a TBR cutoff of 0.46 was applied, 17/45 previously “cold” masses were reclassified as “hot” (13 RCC, 1 non-RCC malignancy, 6 oncocytomas). When a TBR cutoff of 0.6 was applied, 6/45 previously “cold” masses were reclassified as “hot” (1 RCC, 1 non-RCC malignancy, 4 oncocytomas) while 1 previously “hot” RCC was reclassified as “cold” (Figure 1). TBRs could not be calculated for 2/52 masses. Using TBR cutoffs of 0.46 and 0.6 improved the negative predictive values of 99mTc-sestamibi SPECT/CT to 89% and 88% but increased the rate of “hot” malignant tumors to 23.1% and 3.8%, respectively.

Conclusions: Quantitative TBR cutoffs for 99mTc-sestamibi SPECT/CT offer only slight improvement in predicting oncocytomas. However, this method classifies more RCCs as "hot". Further research is needed to evaluate 99mTc-sestamibi SPECT/CT's clinical utility.

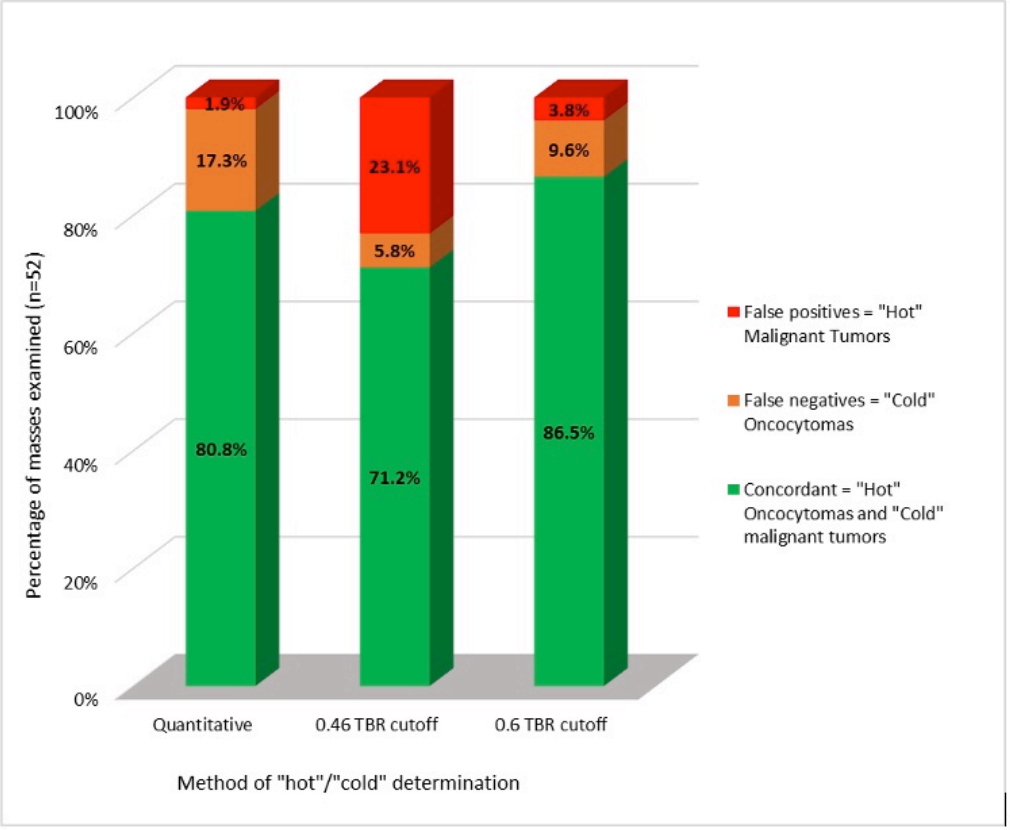

Figure 1 – ^{99m}TC-Sestamibi SPECT/CT concordance between quantitative and qualitative methods of interpretation

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Outcomes of virtual reality mask as a distraction tool within functional urological interventions performed under local anesthesia

European Urology Open Science 2024;60 (Supplement 1): S21

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Introduction & Objectives: The aim of this pilot study was to evaluate the outcomes of virtual reality (VR) mask during minimally invasive functional urological interventions to reduce pain and distress.

Materials & Methods: From December 2021 to December 2022, a single-center observational prospective pilot cohort study included all consecutive patients undergoing intradetrusor botulinum toxin injection, sacral neuromodulation and urethral bulking agent injection with combined anesthetic protocol composed by local anesthesia + VR mask (Hypno VRTM virtual reality mask, Strasbourg, France). All patients expressed written informed consent. Patients with cognitive or sensorial impairment were excluded. Pre-operative and postoperative evaluation included the State-Trait Anxiety Inventory (STAI index), a 4-point Likert Anxiety rating scale, a visual analog score (VAS score) for pain, two “ad hoc” questionnaires (1: are you satisfied with the procedure? 2: would you recommend the procedure to a friend or a familiar?) and the registration of intraoperative vital signs. The primary outcome was the evaluation of mask-related complications. Secondary outcomes included patient's reported intraoperative pain and anxiety. Any statistical difference between intraoperative and postoperative parameters was evaluated through either the Chi2 test or the paired samples t-test or the Wilcoxon's test for paired samples, as appropriate.

Results: Overall, 39 patients were included in the study: 21 patients underwent intradetrusor botulinum toxin injection, 10 sacral neuromodulation and 8 urethral bulking agent injection. Mean age was 63.9+-14.8 years. Eleven patients (28%) were affected by neurological conditions (spinal cord lesions, multiple sclerosis and Parkinson's disease). Comorbidities existed in 16 patients (41%), including hypertension, heart disease, diabetes, major depression, hypothyroidism. Any mask-related complication was observed, nevertheless 2 patients self-removed the mask during the intervention due to subjective discomfort. Pre-operative and intra-operative mean arterial pressure were respectively 105.4+-18.8mmHg and 111.7+-17.1mmHg (p=0.01). Preoperative and intra-operative mean heart rate were 72.7+-12.2bpm and 75.2+-13.2bpm (p=0.12). Preoperative and postoperative STAI index were 34.8+-10 and 32.8+-10.3 (p=0.88). Mean Likert anxiety scale value was 2.2+-1.1, mean intraoperative VAS score was 5.3+-2.5. Thirty four (87%) patients declared themselves satisfied by the surgical procedure; 36 (92.3%) patients would have recommended the same procedure to a relative in case of need.

Conclusions: Our pilot study confirmed the safety of the use of VR mask within anesthetic protocol for minimally invasive functional urological interventions. Moreover VR mask can be useful in preventing anxiety and reducing pain. Further comparative studies are needed.

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MI-CRONS: A novel practical classification for male urinary incontinence

European Urology Open Science 2024;60 (Supplement 1): S22

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Introduction & Objectives: The objective of this study is to develop a new simple and practical classification of male urinary incontinence based on the clinical features and type of urinary incontinence.

Materials & Methods: MI-CRONS classification is a system based on two estimations: a) severity of incontinence and b) patients' characteristics that would play a role in management and further prognosis. Clinical evaluation of incontinence severity is based on preservation of self-voiding, proportion of void/lost urine, absorbable device usage, level of physical efforts that causes urine loss and nocturnal incontinence. Following patients' characteristics of patients were included in classification system: history of radical prostatectomy, history of pelvic radiation, surgery for prostatic obstruction, neurogenic incontinence and urethral stricture. This classification system uses five uppercase Latin letters as follows: Male Incontinence – Cancer, Radiation, Obstruction, Neurogenic, Stricture. (Figure 1) We presume that the MI-CRONS classification could be used for stress, urgency, and mixed incontinences.

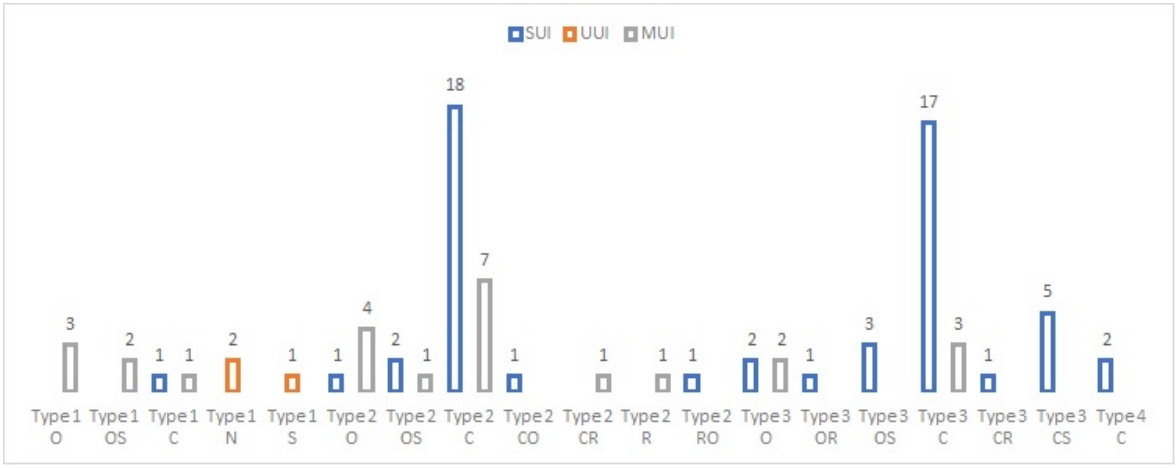
Figure 1. MI-CRONS Classification system

	Incontinence severity			
Patient's characteristics	**Type 1 (Mild)** • Urination is preserved • There is a minimal urine loss, usually during physical efforts. • No need for multiple absorbent pads/diapers, external urine collection devices. • No nocturnal or posturnal enuresis. • Significant physical efforts for UI	**Type 2 (Moderate)** • Urination is mainly preserved • The loss of urine is less than the amount of voided urine • Normally, no need diapers or external urine collection devices • Nocturnal or posturnal enuresis is unlikely • Average physical for UI, often at the end of the day	**Type 3 (Severe)** • Urination is partially preserved • The loss of urine exceeds the amount of voided urine • Usually, patients use absorbent diapers, external devices for urine collection • Nocturnal of posturnal enuresis possible • Minimal physical efforts causes UI	**Type 4 (Total)** • Urination is almost absent • Almost total urine loss • Patients require permanent absorbent diapers, extensive use of external urine collection devices • Nocturnal and posturnal incontinence is typical
C – Cancer: patients after radical prostatectomy for prostate cancer or any other reasons.				
R – Radiation: Patients after external radiotherapy or prostate brachytherapy.				
O – Obstruction: Patients after surgical management				

of benign prostatic obstruction caused by benign prostate hyperplasia, bladder neck stricture or other reasons.				
N – Neurogenic: patients with neurogenic or non-neurogenic bladder disorders				
S – Stricture: patients with urethral stricture, urethra-vesical anastomosis stricture and other sources of obstruction not related to the prostate.				

Results: A single institution longitudinal observational study (2020-2022) included 85 male incontinent patients (~ 67 yo.). Patients were classified by MI-CRONS in order to estimate an inclusiveness and complicity of proposed classification. Only one patient could not be classified using the MI-CRONS classification due to the fact that the patient has a history of bladder exstrophy, augmentation cystoplasty. (Figure 2)

Figure 2. Distribution of the patients by MI-CRONS



Conclusions: The MI-CRONS has demonstrated prompt potential for classifying male incontinence of any type. It is a valuable tool for daily practice and clinical trials. A multicenter trial and Delphi consensus would be proposed with international experts for the further development of MI-CRONS.

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Do phosphodiesterase type 5 inhibitors increase the risk of biochemical recurrence after radical prostatectomy?

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Introduction & Objectives: There have been conflicting studies on the association between phosphodiesterase type 5 inhibitor (PDE5i) use and biochemical recurrence (BCR) following radical prostatectomy (RP). The aim of this analysis was to determine whether PDE5i drug exposure after RP increases the risk of BCR.

Materials & Methods: An institutional database of prostate cancer patients treated between January 2009-December 2020 was reviewed. BCR was defined as two PSA measurements greater than 0.1 ng/mL. PDE5i exposure was defined using a 0-3 scale, with 0 representing never used, 1 sometimes used, 2 regular used and 3 routinely used. The risk of BCR with any PDE5i exposure, the quantity of exposure and the duration of PDE5i exposure were assessed by multivariable Cox proportional hazards models.

Results: The sample size included 4630 patients, with 776 patients (16%) having BCR. The median follow-up for patients without BCR was 27 (IQR 12, 49) months. 89% reported taking a PDE5i at any time during the first 12 months after RP and 60% reported doing so for 6 or more months during the year after RP. There was no evidence of an increase in the risk of BCR associated with any PDE5 inhibitor use (HR 1.05, 95% CI 0.84, 1.31, p=0.7) or duration of PDE5i use in the first year (HR 0.98 per 1 month duration, 95% CI 0.96, 1.00, p=0.055). Baseline oncologic risk was lower in patients using PDE5i, but differences between groups were small, suggesting that residual confounding is unlikely to obscure any causal association with BCR.

Conclusions: Prescription of PDE5i to men after RP should be based exclusively on quality of life considerations and patients receiving PDE5i can be reassured that their use does not increase the risk of BCR.

23

Repair of traumatic urethral strictures. How frequent are the different steps of the elaborated perineal posterior urethroplasty performed?

European Urology Open Science 2024;60 (Supplement 1): S25

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Introduction & Objectives: The management of traumatic urethral strictures remains a challenge for urologists. In most cases, the existing defect between the urethral ends is small, and the ideal treatment is end-to-end perineal urethroplasty. Cases with extensive strictures that are left with long defects may require the use of four different sequential maneuvers to achieve a tension-free anastomosis. The objective of this review is to analyze the success rate of this surgery and the percentage of cases that require more than two sequential maneuvers to perform the urethroplasty.

Materials & Methods: A retrospective analysis of 116 patients who underwent urethroplasty for urethral stricture after blunt perineal trauma at our center between 1965 and 2020. Demographic data, date, mechanism of action of the trauma, emergency management, previous urethral interventions, surgical technique carried out, complications, presence of erectile dysfunction and urinary incontinence were collected.

Results: 82 patients (70,7%) presented with pelvic fracture. The most frequent form of trauma was traffic accident (68%), followed by crushing (24%). Suprapubic cystostomy was placed in 50.2% and urethral realignment performed in 25.3%. The mean stricture length was 2.2cm, affecting mostly membranous urethra (67%). During surgery it was necessary to separate the corpora cavernosa in 61.5% and partial pubectomy was performed in 18.8% of the cases. Urethral re-routing was not done in any patient. Erectile dysfunction developed after trauma in 40.5% of cases and new erectile disfunction was noted in 4.3% patients after surgery. Surgery was successful in 91.3% of cases with a median follow-up of 16 (6-47) months.

Conclusions: Conclusion:
Deferred anastomotic urethroplasty offers a high success rate in traumatic urethral strictures. We perform corporeal body separation in a higher percentage of cases than described in the literature, which may explain why in our series no patient required urethral rerouting.

24

Declining popularity of continent urinary diversion: An extensive two-decade nationwide trend analysis based on total population data from Germany

European Urology Open Science 2024;60 (Supplement 1): S26

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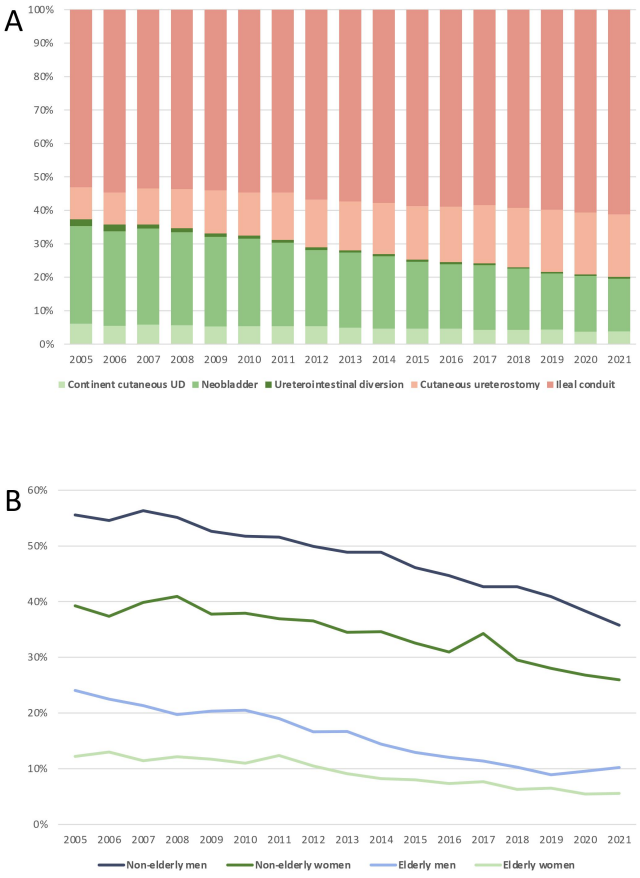
Introduction & Objectives: Continent urinary diversions (CUDs) are an important reconstructive bladder replacement strategy after extirpative procedures due to malignant or benign bladder conditions. Recent data indicate a global decline in the use of CUDs. However, nationally-representative data from developed countries are lacking. We aimed to confirm this trend in a contemporary, nationwide, total population analysis from Germany.

Materials & Methods: We analyzed Diagnosis Related Groups (DRG) billing data from the German Federal Statistical Office (Destatis). The analysis included clinical characteristics such as age, gender, and annual procedural counts in every federal German state. UDs were extracted using operative and procedure-specific (OPS) codes and stratified into continent (neobladder, continent cutaneous UD, ureterosigmoidostomy) vs. incontinent (ileal conduit and cutaneous ureterostomy). We examined temporal trends of CUD use in the overall cohort and stratified by gender and age. *t* and Mann-Whitney U tests as well as linear regression models were used for statistical analyses.

Results: Among the 157 970 UDs performed between 2005 and 2021, 44 187 were CUDs (28%). The proportion of CUDs declined linearly over the last 17 years (37% in 2005 to 20% in 2021) with an estimated annual percentage change (EAPC) of -3.9% (P<0.001). These findings

were consistent across gender and age groups (***Figure 1***).



Conclusions: While the underlying reasons and promoters of this development require further investigation, hypotheses include the proportional uptake of robot-assisted surgery. In the era of personalized medicine, patients should have the opportunity to choose therapies that best suit their individual needs/expectations. Future research is needed to determine whether these trends affect the quality of patient care or indeed limit the diversity of treatment options available.

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Platelet-Rich Plasma (PRP) as an Interposing Layer in the Repair of Radiation-Induced and Recurrent Vesicovaginal Fistula

European Urology Open Science 2024;60 (Supplement 1): S28

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Introduction & Objectives: To test the efficacy and feasibility of using the platelet-rich plasma (PRP) as an adjunct for better tissue healing in the repair of radiation-induced vesicovaginal fistulae (rVVF) and recurrent vesicovaginal fistulae via the transvaginal route

Materials & Methods: 12 patients with rVVF and recurrent (VVF) were included in this pilot trial. These included 5 patients of (rVVF) and 7 patients of recurrent (VVF) with moderate to severe fibrosis. Patients were evaluated after one month, 3 months and 6 months postoperatively. All patients were repaired via the transvaginal route using Latzko technique. After circumcising the fistulous opening and separating the vaginal mucosa off the fistula all around, the fistula was closed without trimming or excision. PRP prepared from the patient's own blood was prepared and instilled over the fistula site after its closure. The vaginal mucosa was then closed

Results: Total success rate was 83.3%. Ten patients were completely dry at all time intervals postoperatively. We had two failures, one within each group of the (rVVF) and the recurrent (VVF) groups. The fistula site was very close to the bladder neck and with wide defect of 1.7 cms in the (rVVF) case and the other recurrent case with dense fibrosis ended in a smaller fistula. No blood loss was encountered using this technique, and mean operative time was 38.6 minutes ± 4.7

Conclusions: The use of the PRP as an adjunct in the repair of rVVF and recurrent (VVF) seems to be effective, simple to prepare and use, and without any increased morbidity. It may have a role in the regenerative process and better healing of these kinds of fistulae when vaginal tissue is scarred, and the blood supply is so much compromised. The operative time was comparable to the classic vaginal repair with vaginal flaps.

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Risk factors for the appearance of lithiasis in the long-term follow-up of pediatric pyeloplasties

European Urology Open Science 2024;60 (Supplement 1): S29

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Introduction & Objectives: The Anderson-Hynes technique has been the technique of choice for correcting UPJ syndrome. However, despite the track record of this technique, the long-term complication of upper urinary tract lithiasis is little known. The objective of this study is to determine risk factors that influence the occurrence of lithiasis in the long-term follow-up of patients undergoing pyeloplasty.

Materials & Methods: MATERIALS AND METHODS We retrospectively reviewed 144 medical records of patients who underwent pyeloplasty at a single institution from 1988 to 2022. Finally, 72 patients were included in the analysis, and demographic data, preoperative data, surgical approach, postoperative drainage, postoperative data, lithiasis occurrence, need for surgery, and follow-up time were collected. Uni-, bi-, and multivariate analyses were performed using logistic regression, as well as survival analysis using Kaplan-Meier curves and Cox regression.

Results: Demographic and preoperative data are summarized in Table 1. The incidence of lithiasis was 16.7%, with an average of 6.7 years. In the multivariate analysis, only DPR prevailed as a risk factor (OR 1.17; $p<0.023$; 95% CI 1.021 to 1.331), while a greater difference in DPR was a protective factor in the occurrence of lithiasis (OR 0.75; $p<0.036$; 95% CI 0.57 to 0.98). Regarding lithiasis-free survival curves, the older age group (>10 years) had the worst survival. In the Cox regression of the predictive model, for every additional millimeter in preoperative DPR, the risk of lithiasis occurrence multiplies by 1.2 ($p<0.000$; 95% CI 1.085 to 1.315).

Conclusions: Patients with preoperative renal pelvises of larger diameter that do not significantly decrease in the postoperative period have an increased risk of presenting lithiasis during follow-up, and those who tend to do so more quickly are patients who undergo surgery after 10 years. Therefore, it may be important to establish follow-up schemes that extend up to the first 10 postoperative years

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Becoming editor-in-chief of European Urology Oncology: The 4 pillars of the development strategy

European Urology Open Science 2024;60 (Supplement 1): S30

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Introduction & Objectives: The field of genito-urinary malignancies is extremely broad. It naturally concerns prostate cancer, kidney cancer and bladder tumours, not forgetting testicular cancer, upper urinary tract, adrenal glands or retroperitoneum. The management of these cancers now requires complex, almost encyclopaedic and constantly evolving medical and surgical knowledge. This cross-disciplinary knowledge covers organs and physiology, surgery, drugs (including immunotherapy, chemotherapy and targeted therapies) and radiotherapy methods.In this spirit, European Urology Oncology (EUO) supports the pursuit of a multi-disciplinary approach by delivering high quality science and research in genito-urinary malignancies. My purpose was to elaborate a plan of development for European Urology Oncology.

Materials & Methods: The EAU sections, guidelines and working groups were originally formed to address the three core missions of our scientific society: 1. Science and research 2. Education and training 3. Professional practice
EUO with a current impact factor of 8.512, represents an important specialty resource within the family Journals of the European Association of Urology (EAU); a sister journal to European Urology, European Urology Focus and European Urology Open Science. It serves its urology readers with a complementary blend of peer-reviewed original articles, opinion piece editorials and topical reviews on a wide range of issues relating to urological cancers.
The EAU has been calling upon its membership for applicants for the position of Editor-in-Chief of EUO in January 2023. The applicants had to present a strategy for EUO aimaing at:
- Maintaining content quality and scientific rigor
- Broadening the readership and addressing the needs of our specialty
- Measures for demonstrating the reach of the journal beyond the Impact Factor
- Measure to improve diversity, equality and inclusivity among the editorial team

Results: My statement of interest was sent in due time with a plan of development based on 4 distinct pillars:
- Nurturing scientific content
- Boosting impact and metrics
- Expanding collaboration within EAU and beyond
- Reshaping EUO Editorial Board

I was interviewed by the executive committee on February 7, 2023 and officially announced as the new EIC of EUO during EAU23 in Milan. After a transition period, during the last months, the new editorial team is now fully on charge as of 1st, September 2023.

Conclusions: In an era of evidence-based medicine where everything is highly organised and rational, there is also a role for subjectivity in choosing a new EIC. Becoming EIC of a scientific journal of a major scientific society is a very exciting challenge for an academic. Cancer raises very important scientific and financial issues. EAU must become a brand in the field of GU cancers and from this point of view, the EUO is a major asset in this winning strategy in the short, medium and long term.

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Automated analysis of the uroflometry curve

European Urology Open Science 2024;60 (Supplement 1): S31

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Introduction & Objectives: Uroflowmetry is a low threshold, non-invasive, diagnostic tool in patients with lower urinary tract symptoms. Besides numerical data, the graphic depiction of the uroflowmetry curve contributes in the diagnostic process. Basic shapes of the uroflowmetry curve are described in literature: bell-shaped, fluctuating, intermittent and plateau. Nevertheless, assessment of the shape of the uroflowmetry curve is subjective and not standardised. As a result, underlying pathology may be missed and the effect of therapy cannot be adequately evaluated. The aim of this study was to develop a tool to improve assessment of the uroflowmetry curve.

Materials & Methods: The basic shapes of the uroflowmetry curve (bell-shaped, fluctuating, intermittent and plateau) were defined in MATLAB by creating a question panel. A uroflowmetry curve could have characteristics of several basic shapes. Based on the algorithm, different series of real life uroflowmetry curves were analysed by MATLAB. The descriptions generated by MATLAB were reviewed by an expert panel and vice versa: curves assessed by the expert panel were compared with the assessment of MATLAB. Because in the opinion of the expert panel the description ‘long tail' was missing in the set of basic shapes, 'long tail' was added as an extra basic shape. After extensive discussion, all threshold values set in MATLAB were adjusted step by step. Different graphical representations were tested and adjusted.

Results: At the end of the review process, the automated description of the curve was to the satisfaction of the expert panel and a group of the internal users. We developed an online application that real time processed, analysed and displayed uroflowmetry data stored on the hospital server. The description generated by the application could be copied into the electronic patient file. By pressing one of the buttons in the application, explanation and justification of the description could be made visible. For optimal visual assessment, the ideal bell shaped curve based on patient's voided volume was projected over the actual curve. Besides assessing the most recent uroflowmetry curve, it was

also possible to analyse previous ones and to mutually compare them.

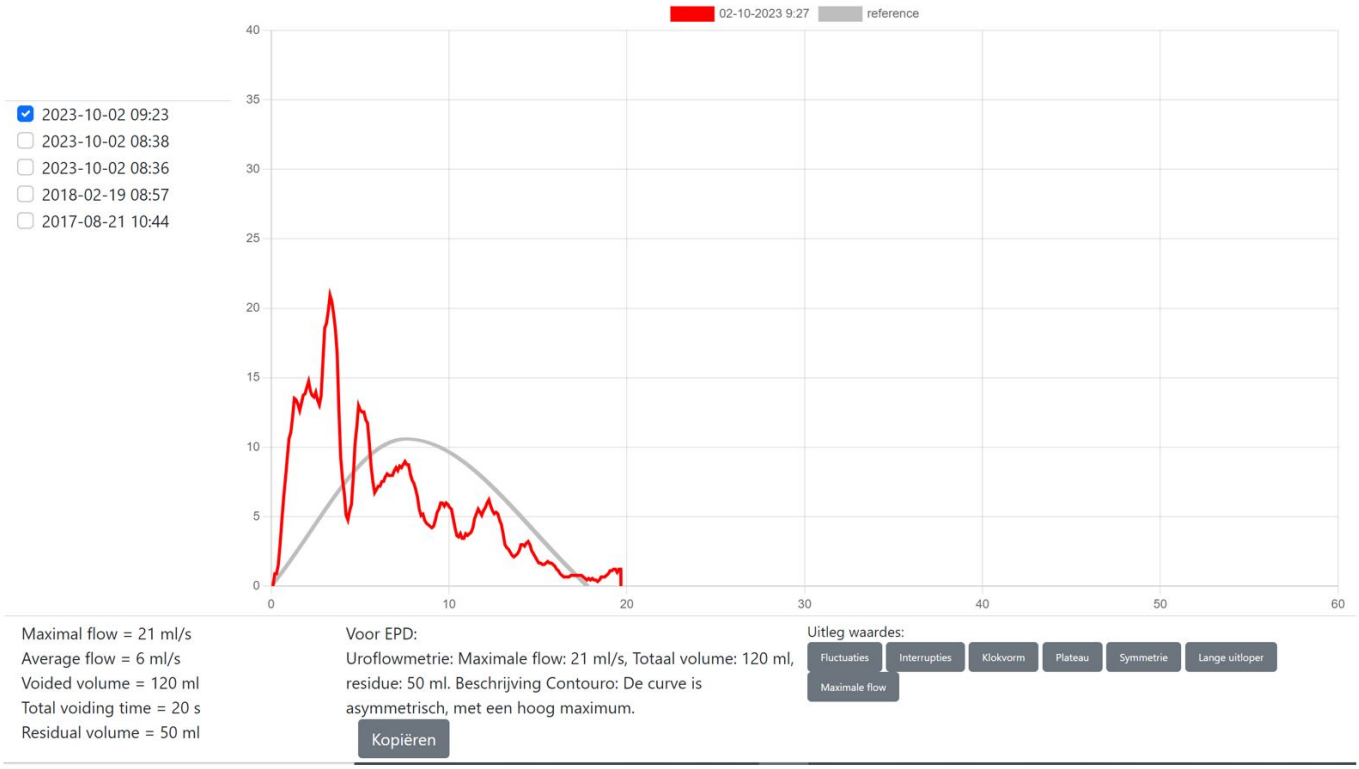

Figure 1. Example of an automatically analysed uroflowmetry curve.

Conclusions: This study has led to a standardised description of the uroflowmetry curve and the possibility of automated analysis by an online application. The next step is validation of the application in a larger group of users.

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Surgisense - adding sense to vision-guided surgery: Fingertip molecular sensing

European Urology Open Science 2024;60 (Supplement 1): S33

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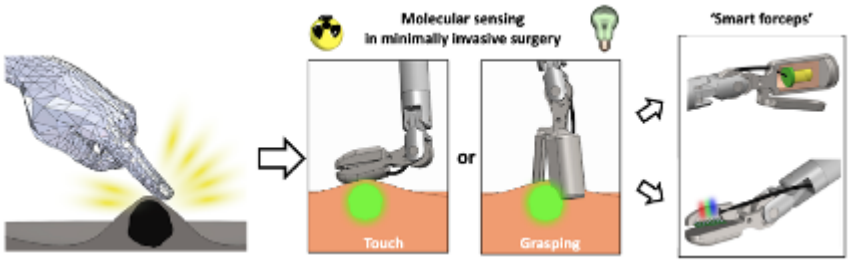
Introduction & Objectives: Image-guided surgical techniques hold great promise for the future of surgical urology by allowing better intraoperative assessment of anatomical structures. Being able to not only visually assess tissue characteristics but also have instruments recognise the handled tissue has the potential to refine surgery. Instrument-integrated ‘fingertip molecular sensing' provides complementary value in the same way as the human touch complements vision.

Materials & Methods: We applied ‘click-on' modalities to push towards ‘smartforceps' that combine tissue manipulation with sensing of relevant fluorescent and/or radiotracers for robotic surgery, in a development track from design and preclinical (animal) studies to training and surgical implementation. Goal is to make fingertip molecular sensing available for daily practice. The technology, when developed can be applied to sense a multitude of tissue specific tracers either through radioactive or fluorescence signaling.



Results: Click-on design probe prototypes were developed and tested in the pig model to sense near-infrared tracers during robotic surgery. The resulting Click-On device allowed for NIR indocyanine green (ICG) signal identification down to a concentration of 4.77 x 10–6 mg/ml. The fully assembled system could be introduced through the trocar and grasping, and movement abilities of the instrument were preserved. During surgery, the system allowed for the identification of blood vessels and assessment of vascularization (i.e., bowel, bladder and kidney), as well as localization of pelvic lymph nodes. During human specimen evaluation, it was able to distinguish sentinel from non-sentinel lymph nodes. With a €1.4 million EURO Dutch NOW grant and in-kind industry support (Intuitive, Crystal Photonics, SurgicEye, DEAM, DEMCON) we will further develop the click on fingertip molecular sensing technology developing hard and software as well as perform the necessary clinical first-in-men studies.

Conclusions: With this introduction of a NIR-fluorescence Click-On sensing detector, a next step is made towards using surgical instruments in the characterization of molecular tissue aspects.

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Functional and perioperative outcomes of a standardized ICG fluorescence-guided robot-assisted and endoscopic approach for treatment of ureteral strictures with use of buccal mucosa graft in selected cases

European Urology Open Science 2024;60 (Supplement 1): S34

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Introduction & Objectives: Aim of the study is to evaluate feasibility and outcomes of a standardized ICG fluorescence-guided robot-assisted and endoscopic approach for treatment of ureteral strictures with use of buccal mucosa graft in selected cases.

Materials & Methods: All patients who were surgically treated for a ureteral stricture with the described approach with a minimum follow-up of 12 months were revised. Pelvic strictures were treated with uretero-vesical reimplantation with or without psoas hitch, while lumbar and iliac strictures with either tension-free end-to-end anastomosis if ≤ 2 cm or ureteroplasty with buccal mucosa graft if > 2 cm. A transperitoneal approach with the daVinci Xi robotic system was carried out. Transillumination with flexible ureteroscopy and ICG fluorescence were used intraoperatively to identify the lower edge of the stenosis and the healthy ureteral margins for anastomosis. Transnephrostomic ICG injection was used to define the upper edge of the stricture. Patients were followed-up with serum creatinine levels and eGFR values at 3 and 12 months, CT scan and renal scan at 3 months.

Results: 31 patients were included. Median stenosis length was 15 mm (IQR 12-30). Median operative time was 180 minutes (IQR 162.5-225) and median blood loss 100 ml (IQR 50-100). Seventeen (53.1%) segmental ureteral resections with end-to-end anastomosis, 10 (31.2%) uretero-vesical reimplantations and 4 (12.5%) ureteroplasties with buccal mucosa grafts were performed. One patient developed a grade IIIb complication. At baseline, mean creatinine was 1.2 mg/dl (SD±0.1) and mean eGFR was 70.8 ml/min/m2 (SD±4.2). After urinary diversion (either JJ stent or nephrostomy tube), mean creatinine was 1.1 (SD±0.1) and mean eGFR was 80.8 (SD±4.3), reflecting improved renal function of -10% in creatinine and +19,6% in eGFR levels. At 3 months after surgery, a further increase was observed (-5.2% in creatinine and +12.2% in eGFR levels). Furthermore, renal function remained stable at 12 month after surgery. At a median follow-up of 30 months only one stricture recurred.

Conclusions: The described standardized surgical approach is useful to optimize surgical treatment of ureteral strictures. It allows a safe preparation of the ureter and a clear definition of the edges of the stricture, thereby guiding a precise and correct incision of the ureter. This enables the surgeon to perform the best suited technique for ureteral reconstruction in each case and potentially to optimize perioperative and functional outcomes. The described standardized surgical approach is feasible, effective and adds little operative time in experienced surgical teams. Importantly, it is associated with a low recurrence rate and confers a significant improvement of renal function at 3 months, which remains stable at one-year follow-up.

31

Enhancing informed consent in laparoscopic radical prostatectomy through hyper-realistic simulation-based tools

European Urology Open Science 2024;60 (Supplement 1): S35

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Introduction & Objectives: Favorable outcomes in endourological procedures by our team, have prompted the undertaking of this study in laparoscopic surgery. The intention was to enhance the support tool to facilitate comprehensive understanding of all aspects of informed consent (procedure, benefits, risks, and alternatives). Based on the acquired experience, minor methodological modifications have been implemented. Additionally, a broader range of factors related to comprehension and decision-making have been assessed. The choice of laparoscopic radical prostatectomy (LRP) as the surgical intervention was made due to its frequency, significance, and the importance of potential associated side effects.

Materials & Methods: A multicenter, prospective, randomized, non-masked controlled study was conducted. Two groups were designed: control and intervention. The study received approval from the Research Ethics Committee of the Autonomous Community of Aragón during the period from November 2020 to November 2021. The randomization method employed envelopes to assign each patient to either the control or experimental group, resulting in the inclusion of 52 patients in each group. Two groups were designed: a control group and an experimental group. Following randomization, each patient was allocated to one of the groups. Five surveys were utilized to measure aspects of subjective and objective comprehension, factors related to decision-making, and features of the tool used. In the control group, traditional informed consent was obtained following the guidelines of the Spanish Association of Urology, while in the experimental group, digital consent was acquired. An interactive presentation was designed with the aim of improving both subjective and objective comprehension and included hyper-realistic simulations. Age, educational level, and economic status were also analyzed.

Results: The degree of subjective comprehension improved by approximately 10% in LRP (72.77 ± 16.53 vs. 62.89 ± 18.92, p=0.008). No significant differences in subjective anxiety were observed. Objective comprehension in LRP improved by approximately 15% (74.78 ± 13.03 vs. 59.57 ± 19.18, p<0.001). No differences were evident in decisional conflict or satisfaction with the decision. The observed improvements were sustained in patients with basic education levels.

Conclusions: Interventions based on hyper-realistic simulations enhance both subjective and objective comprehension in urological patients and, consequently, improve informed consent.

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Trends of European School of Urology (ESU) training and resident education: An overview of 2 decades of EAU education programme

European Urology Open Science 2024;60 (Supplement 1): S36

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Introduction & Objectives: Over the last 2 decades, various education/training programmes have been launched by ESU on behalf of EAU Education Office. These include e-learning platforms, in-person meetings, courses, podcasts, webinars, sub-specialisation meetings and the European Urology Resident Education Programme(EUREP), all to achieve standardise in urological education(SISE) and training. EUREP is the largest teaching and hands-on-training and simulation course worldwide, taught annually over 5-days.

Materials & Methods: Data from last 2 decades of all ESU activities were collected by the EAU/ESU office and analyzed for attendance, geographical, gender and age trends. Demographic data of registrations and attendances to EUREP were also monitored and analysed. A descriptive analysis of participations and trends is provided.

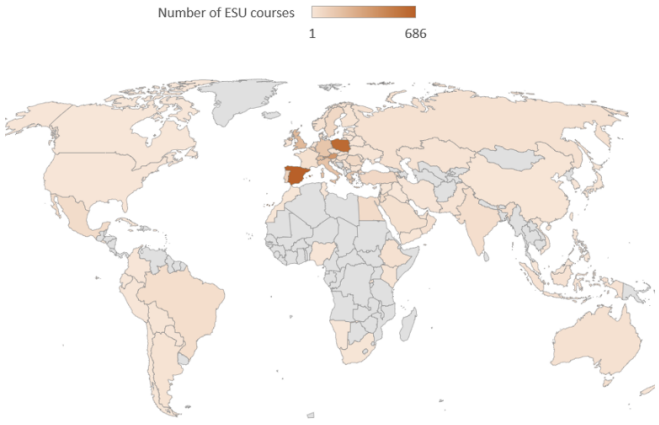


Fig. 1 Geographical distribution of ESU courses completed worldwide until 2022.

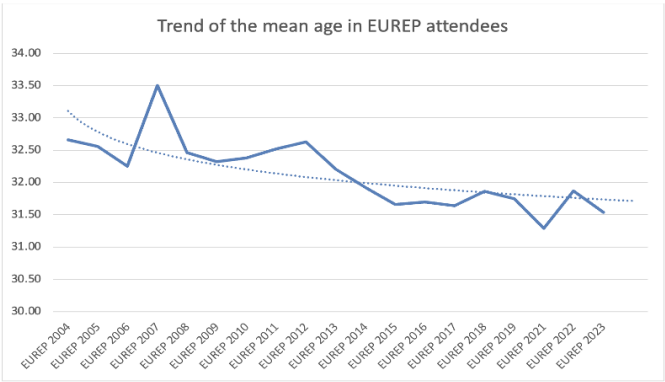


Fig. 3 Mean age of EUREP attendees among the yearly editions (full line), and the respective trend line showing the decreasing trend (dot line).

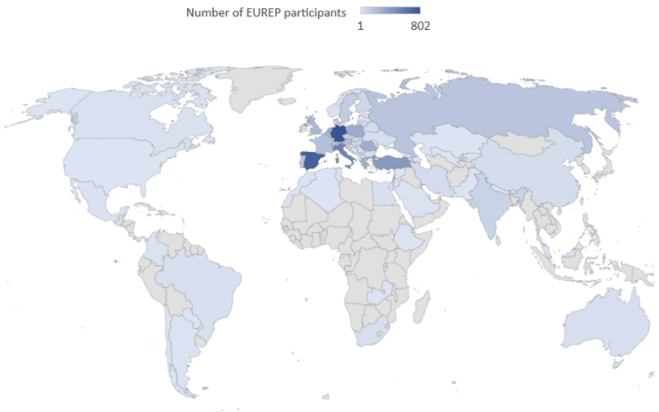


Fig. 2 Geographical distribution of overall EUREP participants.

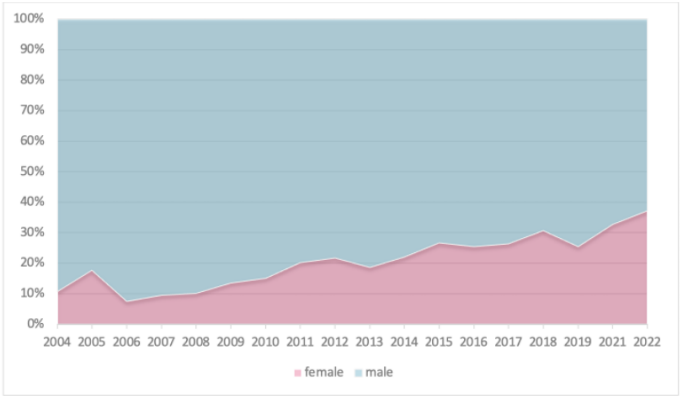
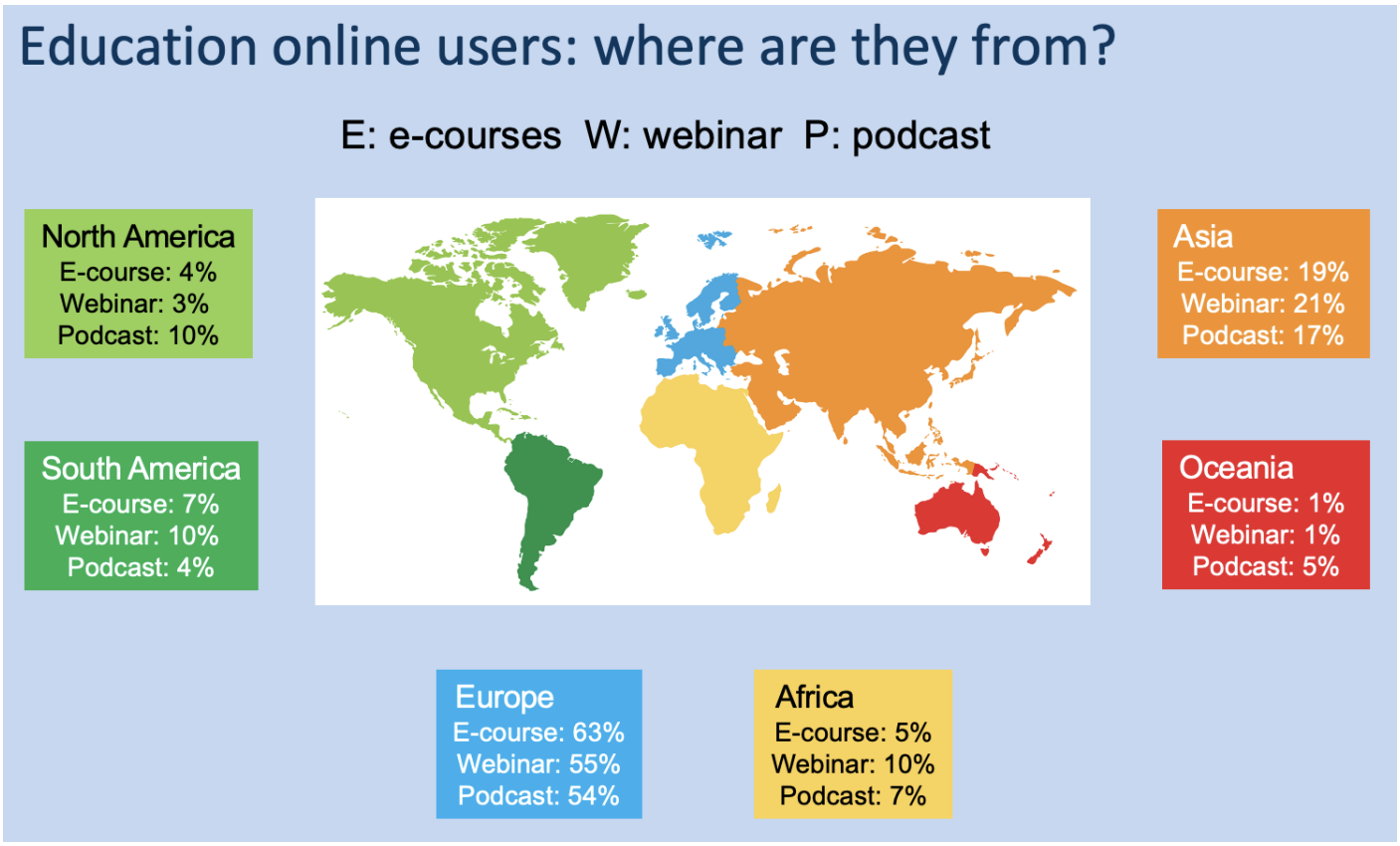


Fig. 4 Gender ratio of attendees to the different editions of EUREP.

Results: A total of 4750 participants have completed ESU courses (including guideline, specialization and webinar courses) with over half of these being webinar courses during COVID pandemic. Similarly, 5958 trainees attended the EUREP from 2004-2022 of which the male:female ratio was 3.75:1. However, the proportion of females increased 3.5-fold from 10.7% in 2004 to 37.1% in 2022($p<0.001$). The overall attendance ratio increased (599 in 2023, from 295 in 2007)($p<0.001$). The mean age of participants is significantly and constantly

decreasing (32.6 years in 2004 to 31.54 in 2022), with a mean yearly decrease by - 0.18%($p<0.001$).



Conclusions: EUREP courses have ncreasing interest/participation from young urologists across Europe. Over time, trainee age has decreased with a surge in female trainees. If this trend continues, we will have gender neutrality within next 5 years. ESU is providing all modes of education/training across the world with both virtual and in-person meetings and courses, which would help in the development and preparation of urologists of the future and best patient care.

33 Single Port SARA (Supine Anterior Retroperitoneal Approach): A new way of robotic surgical management of the entire Gerota's content

European Urology Open Science 2024;60 (Supplement 1): S38

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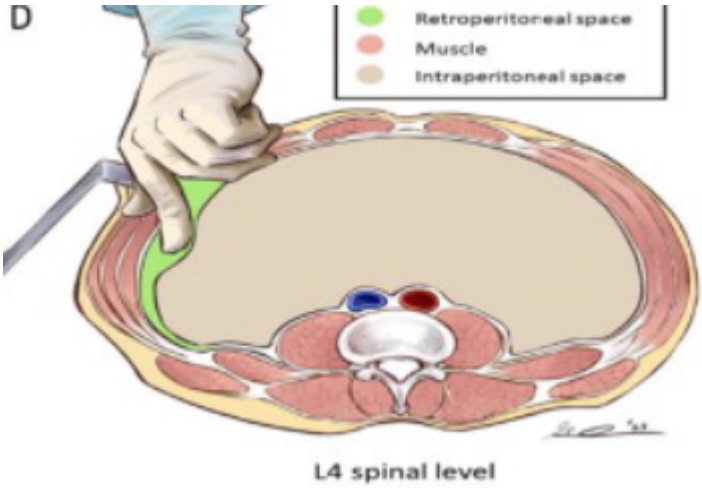
Introduction & Objectives: Urologic surgery was originally most completely retroperitoneal. Eventually urologists traded off this access for the introduction of laparoscopy and eventually multiport robotics, techniques which needed more space to be performed. The recent introduction of the Single Port platform allowed us to go "back to the future" and perform robotic surgery using a new, less invasive way to access for the first time the entire urinary tract retroperitoneally through a single, anterior incision site with the patient supine. The objective of this paper is to describe the technique and report early outcomes.

Materials & Methods: Surgical technique: The patient is in a supine position. A rubber roll placed under the ipsilateral flank. Access to the retroperitoneum is via a 30-mm incision at approximately the 3 cm medial and 3 cm caudal to the anterior superior iliac spine. The retroperitoneal space is accessed bluntly. Next, finger dissection is used to create a small working space (Fig 1). No dilating balloon is required. The robotic access port (Intuitive Surgical, Sunnyvale, CA, USA), is then inserted into the incision and oriented towards the reference anatomy. Clinical outcomes: Preoperative, intraoperative and postoperative parameters have been retrospectively collected for every procedure conducted through the sara access.



Results: 76 patients underwent single port robotic surgery through SARA access since 10/2022. Overall and procedure specific peri and postoperative outcomes are reported in table 1.

Age (avg)	54
Sex (n)	
Male	32
Female	44
BMI (avg)	31.7
ASA score ≥ 3 n (%)	54 (71%)
Postop complications n (%)	4 (5.2%)
Intraop complications n (%)	0
EBL (avg)	137.5 ml
Same Day Discharge n (%)	59 (77.6%)

RAPN RARN Pyeloplasty & Ureteroplasty Ureteral reimpl Nephroureterectomy Adrenalectomy Pyelolithotomy Ureterolithotomy	39 16 7 3 2 3 5 1
Type of complications (n)	(Clavien Dindo >3)
Retroperitoenal hematoma	2
Retroperitoneal urinoma	1
Urosepsis	1

Other recorded parameters were procedure length, postoperative pain and use of narcotic showing better outcomes when compared to other SP accesses.

Conclusions: Our study results demonstrate the feasibility and safety of the SARA approach for most types of upper urinary tract surgery in the retroperitoneum using the da Vinci SP robotic platform. The SARA approach facilitates and standardizes a retroperitoneal access to treat every organ included in the Gerota's fascia.