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Posterdiskussion I – Prostatakarzinom

Discussion des posters I – Carcinom de prostate

P01 ARCHES: Efficacy of androgen deprivation therapy (ADT) with enzalutamide (ENZA) or placebo

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Background & Goals:

ENZA, a potent androgen receptor inhibitor, has demonstrated benefit in men with castration-resistant prostate cancer. A clinical benefit of ENZA + ADT versus PBO + ADT for men with mHSPC has been shown in the ARCHES trial regardless of prior treatment, including prior docetaxel, radical prostatectomy, and/or radiation therapy. This post hoc analysis evaluated the efficacy of ENZA + ADT in patients enrolled in ARCHES by prior local and systemic treatment.

Materials & Methods:

In ARCHES, a global, double-blind, PBO-controlled, Phase 3 study (NCT02677896), patients with mHSPC were randomized 1:1 to ENZA (160 mg/day) + ADT or PBO + ADT, stratified by disease volume and prior docetaxel therapy. Ethical Committee approval was obtained. The primary endpoint was radiographic progression-free survival (rPFS; scans assessed centrally). Secondary endpoints included time to prostate-specific antigen progression, castration resistance, first symptomatic skeletal event, and new antineoplastic therapy, as well as PSA undetectable rate and objective response rate. Analyses of clinical endpoints were completed by prior local and systemic treatment (including docetaxel, radical prostatectomy, and/or radiation therapy) to assess efficacy of ENZA. Treatment continued until disease progression or unacceptable toxicity.

Results: 1150 men were randomized (ENZA + ADT, 574; PBO +ADT, 576). Baseline characteristics were balanced between groups. Median follow-up was 14.4 months. ENZA + ADT significantly improved rPFS (hazard ratio [HR] 0.39 [95% confidence interval (CI) 0.30, 0.50]; $p < 0.0001$), with similar improvements reported in the prior docetaxel (Yes: HR 0.52 [95% CI 0.30, 0.89]; No: HR 0.37 [95% CI 0.28, 0.49]), radical prostatectomy (Yes: 0.26 [0.11, 0.65]; No: 0.40 [0.31, 0.52]), radiation therapy (Yes: 0.44 [0.21, 0.91]; No: 0.38 [0.30, 0.50]), and local therapy subgroups (Yes: 0.35 [HR 0.19, 0.64]; No: 0.40 [0.30, 0.52]). Treatment benefits were also observed with ENZA + ADT in most secondary clinical endpoints in the overall population and in all prior local and systemic treatment subgroups.

Conclusions: This post hoc analysis demonstrates clinical benefit of ENZA + ADT versus PBO + ADT based on rPFS and secondary clinical endpoints in patients with mHSPC, which is maintained in most evaluated subgroups, irrespective of the prior local and systemic treatments received.

Funding: Astellas Pharma Inc.; Pfizer Inc.

Editorial: Complete HealthVizion

P02 Identifying classes of the psycho-neurological symptom cluster in long-term prostate cancer survivors – Results from the multiregional Prostate Cancer Survivorship Study in Switzerland (PROCAS)

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Background & Aim:

Aside from urological and sexual problems, long-term (≥ 5 years after diagnosis) prostate cancer (PC) survivors might suffer from pain, fatigue and depression. These symptoms are collectively known as the psycho-neurological symptom (PNS) cluster. Little research has been done to 1) identify possible subtypes of this cluster, 2) classify cancer survivors accordingly, and 3) explore associations between subtypes of the PNS cluster and health-related quality of life (HRQoL) in long-term PC survivors. Therefore, with this study we aimed to explore these research gaps.

Methods:

653 stage T1-T3N0M0 survivors were identified from the multiregional Prostate Cancer Survivorship in Switzerland (PROCAS) study. Fatigue was assessed with the EORTC QLQ-FA12, mental health with the MHI-5 and pain with the EORTC QLQ-C30 questionnaire. Latent class analysis was used to derive PNS cluster classes. Factors associated with the derived classes were determined using multinomial logistic regression analysis.

Results:

Three PNS classes were identified: class 1 (61.4%) – ‘low pain, low physical and emotional fatigue, moderate mental distress’; class 2 (15.1%) – ‘low physical fatigue and pain, moderate emotional fatigue, high mental distress’; class 3 (23.5%) - high scores for all symptoms. Survivors in classes 2 and 3 were more likely to be physically inactive, report a history of depression or some other specific comorbidity, being treated with radiation therapy, and having worse HRQoL outcomes compared to class 1.

Conclusion:

Three distinct classes of the PNS cluster were identified, which are associated with treatment, comorbidities, lifestyle factors, and HRQoL outcomes. Therefore, improving classification of PC survivors according to severity of multiple symptoms could assist in developing interventions tailored to survivors’ needs to improve HRQoL outcomes.

P03 Promising perspectives for radionuclide therapy of prostate cancer: Comparison of ¹⁷⁷Lu-Ibu-DAB-PSMA with ¹⁷⁷Lu-PSMA-617

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Background and Aims:

¹⁷⁷Lu-Ibu-DAB-PSMA, a PSMA-ligand comprising ibuprofen as an albumin binding entity, was identified as a promising candidate for targeted radionuclide therapy due to its high tumor accumulation (1). In this preclinical study, the in vivo therapeutic efficacy of ¹⁷⁷Lu-Ibu-DAB-PSMA was investigated and compared to the effect of ¹⁷⁷Lu-PSMA-617, which is currently in Phase III clinical trials (VISION, NCT03511664).

Materials and Methods:

Therapy studies were conducted with mice bearing PSMA-expressing PC-3 PIP tumor xenografts. Mice (n= 6) were injected with saline (control), ¹⁷⁷Lu-Ibu-DAB-PSMA or ¹⁷⁷Lu-PSMA-617 at activity levels of 2, 5 and 10 MBq per mouse. The tumor sizes and body weights of mice were monitored over 3 months until a pre-defined endpoint was reached. Blood plasma parameters were determined shortly before euthanasia.

Results:

At all activity levels, the therapy with ¹⁷⁷Lu-Ibu-DAB-PSMA was more effective than with ¹⁷⁷Lu-PSMA-617. While the median survival time of ¹⁷⁷Lu-Ibu-DAB-PSMA-treated mice (2 MBq) was 34 days, the majority of mice treated with 5 or 10 MBq of ¹⁷⁷Lu-Ibu-DAB-PSMA survived even until the end of the study. In contrast, the median survival time of mice treated with 2, 5 or 10 MBq of ¹⁷⁷Lu-PSMA-617 was only 19, 32 and 51 days, respectively, compared to 19 days for untreated control mice. Plasma parameters were in the same range in treated mice and untreated controls, indicating the absence of early side effects.

Conclusions:

Application of ¹⁷⁷Lu-Ibu-DAB-PSMA was significantly more effective to treat tumors than ¹⁷⁷Lu-PSMA-617. This exciting data warrant more detailed preclinical investigations of ¹⁷⁷Lu-Ibu-DAB-PSMA and open new perspectives for better treatment options of prostate cancer in the future.

P04 Development of a new class of PSMA radioligands comprising ibuprofen as an albumin-binding entity

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Background and Aims:

PSMA-targeted radionuclide therapy with [¹⁷⁷Lu]Lu-PSMA-617 has been proven to be an effective approach for the treatment of metastatic castration-resistant prostate cancer (VISION, NCT03511664) [1]. The aim of this study was the development of new PSMA ligands derived from PSMA-617 with a weak albumin binder and variable linker entities to increase the tumor uptake [2].

Materials and Methods:

Four glutamate-urea-based PSMA ligands containing the albumin binder ibuprofen, which was conjugated directly or via differently charged amino acids, were developed. The albumin-binding properties of the ¹⁷⁷Lu-labeled radioligands were tested in vitro using human and mouse plasma. Affinity to PSMA and cellular uptake was investigated in PSMA-positive PC-3 PIP tumor cells. The tissue distribution profile was assessed in biodistribution and SPECT/CT imaging studies using PC-3 PIP tumor-bearing nude mice. Areas under the curve were calculated to estimate the radiation dose to the tumor and tissues.

Results: In vitro assays confirmed high binding of all radioligands to mouse and human plasma proteins and specific uptake and internalization into PC-3 PIP cells. Biodistribution studies revealed 20 – 40% increased accumulation in PC-3 PIP tumors as compared to [¹⁷⁷Lu]Lu-PSMA-617 and rapid clearance of activity from background organs. The charge of the linker entity strongly influenced the tissue distribution profiles and excretion kinetics of the different radioligands. [¹⁷⁷Lu]Lu-Ibu-DAB-PSMA, the radioligand containing a positively charged amino acid, showed distinguished tumor uptake and highest tumor-to-background ratios.

Conclusions:

Ibuprofen revealed to be a favorable albumin binder in combination with PSMA ligands. [¹⁷⁷Lu]Lu-Ibu-DAB-PSMA emerged as the most promising candidate which warrants more detailed preclinical investigations in view of a clinical translation.

P05 Informative value of histological assessment of tissue achieved during aquablation of the prostate

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Objectives

The aim of this work is to determine the histological validity of the tissue obtained during aquablation of the prostate.

Materials and Methods

The histological significance of the tissue gained by aquablation was systematically examined in a group of 12 patients who were treated consecutively with aquablation at the department of urology at St. Gallen Cantonal Hospital due to benign prostatic enlargement associated with lower urinary tract symptoms. The examination was carried out by an experienced uropathologist. Histological slides were scanned with a digital slide scanner (Pannoramic 250, 3D Histech, Hungary) and then assessed using a slide viewer software (Case Viewer 2.3, 3D Histech, Hungary). The surface areas of the assessable glands were examined and set in relation to the total surface area of the histological material.

Results

Median preoperative prostate size was 64.5 ml (range 40 – 80ml). Median tissue amount gained for histological examination and sent in for pathological examination was 2.5 g (range 1 – 4 g). Generally, the tissue showed severe mechanical destruction and fragmentation. The median proportion of assessable glands was 0.41% (0.06 – 1.38%).

A reliable evaluation of possible Carcinoma or atypical cells was not feasible.

Conclusion

The histological informative value of tissue achieved by aquablation of the prostate is negligible. The low proportion and severe fragmentation of assessable glands not allowing for reliable detection of a putative Carcinoma do not justify costs and efforts arising from histological examination.

P06 Inferior oncological outcomes in men with localised high grade prostate cancer but low PSA

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Introduction:

Results from the Surveillance, Epidemiology and End Results (SEER) and National Cancer Database (NCDB) indicated that among men with localized, high grade prostate cancer, those with low prostate specific antigen (PSA) levels at diagnosis have a worse prognosis compared to men with intermediate PSA levels. This prior analysis was based on data with a median follow-up time of 2-4 years, which is limited given the long natural history of prostate cancer in addition to the limited prostate cancer deaths which occurred.

Methods:

Retrospective analysis of the U.S. Health Professionals Follow-up Study (HPFS). The primary endpoint was lethal prostate cancer defined as death from prostate cancer or development of metastases during follow-up. The association between PSA and lethal prostate cancer event free survival was modeled with restricted cubic splines and cox regression as well as competing risk analysis was performed.

Results:

Of 4908 men with localised prostate cancer with available diagnostic PSA and follow-up, 716 had histologically confirmed Gleason score 8-10 tumors diagnosed between 1988 and 2015. The median age at diagnosis was 70 (interquartile range 66-77) years. Primary treatment included radical prostatectomy (43%), radiotherapy (33%), brachytherapy (8%), hormonal therapy (9%), and watchful-waiting, other or unknown therapies (9%). During a median follow-up of 13 (interquartile range 8-19) years through January 2019, 156 (22%) men progressed to lethal prostate cancer and 259 (36%) non-cancer deaths occurred. After adjustment for clinical stage (T1-2 vs. T3-4), Gleason Score (8 vs 9-10) and treatment received, men with low (below 5 ng/ml) PSA at diagnosis were at higher risk for lethal progression compared to men with intermediate PSA levels (5-8 ng/mL), with hazard ratios of 1.83 (95% CI 1.05 to 3.20). As expected, men with high (above 8 ng/ml) PSA values also had an excess risk of lethal prostate cancer (HR 2.14, 95% CI 1.35-3.40) when compared to those with intermediate PSA levels.

Conclusion:

These results suggest a j-shaped, rather than linear, association of PSA with lethal disease in men with high-grade prostate cancer. These clinical data confirm worse oncological outcomes in men with high grade prostate cancer and low PSA compared to intermediate PSA and suggests that the definition of a highest-risk, localized disease should be expanded to include the low PSA group.

P07 Trends in risk-group distribution and Pentafecta outcomes in patients treated with nerve-sparing, robot-assisted radical prostatectomy: a 10-year low-intermediate volume single-center experience

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Objective:

To evaluate the trends in risk-group distribution and Pentafecta outcomes in patients treated with nerve-sparing (NS), robot-assisted radical prostatectomy (RARP) in a single low-intermediate volume prostate cancer (PCa) center over a 10-year period.

Materials and methods:

We queried a prospectively maintained database for patients who underwent NS RARP between 2009 and 2018 in a low-intermediate volume PCa center. Risk-groups were defined according to the D'Amico classification. Pentafecta outcomes referred to the postsurgical presence of potency and continence, and the absence of biochemical recurrence (BCR), positive surgical margins (PSM), and perioperative complications. The Kruskal–Wallis test, the t test and the Mann–Whitney tests were used when appropriate.

Results:

603 patients underwent NS RARP and 484 patients were evaluated for Pentafecta outcomes. Median postsurgical follow-up was 28 months. Overall, 137 (22.7%), 376 (62.3%), and 90 (15%) patients were diagnosed in the low-, intermediate-, and high-risk groups, respectively. Patients undergoing NS RARP shifted from 33 to 20% in the low-risk group, from 52 to 62% in the intermediate-risk group, and from 10 to 13% in the high-risk group. Patients reaching Pentafecta increased from 38 to 44%. No postoperative potency was the main reason for non-achieving Pentafecta (71%). BCR strongly limited Pentafecta achievement in the high-risk group (61%), but not in intermediate (24%) and low-risk (30%) groups.

Conclusions:

Low-intermediate volume PCa centers show similar trends to high-volume centers regarding risk group distributions over time in PCa patients undergoing NS RARP. We reported an increase in Pentafecta outcomes achievement over time even for experienced surgeons. Pentafecta outcomes achievement is risk-group dependent.

P08 Should we perform contralateral nerve-sparing radical prostatectomy in men with high-risk unilateral prostate cancer?

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OBJECTIVES:

Nerve-sparing radical prostatectomy (NS-RP) offers better preservation of genitourinary function; therefore, it is recommended in all eligible patients. International guidelines recommend against NS-RP in men with high risk features, defined as PSA ≥ 20 $\mu\text{g/l}$, ISUP grade group 4-5 prostate cancer (PCa), and/or suspicion of extracapsular extension (ECE) in order to minimize the risk of positive margins (PM). However, these recommendations do not consider modern risk stratification which offers the possibility to personalize the surgical approach according to the laterality of the high-risk features. The objective of this study was to assess whether contralateral NS-RP can be considered in men with high-risk unilateral PCa.

MATERIALS AND METHODS:

Men with high-risk unilateral non-metastatic PCa undergoing open or robot-assisted laparoscopic RP in our hospital from 2014 to March 2020 were selected. The primary outcome was to define the rate of contralateral pathology-proven ECE, seminal vesical invasion (SMI) and PM at RP specimen. Secondary outcome was to explore potential predictors of contralateral ECE with multivariable analysis.

RESULTS:

93 men with a median age of 64 (IQR 60-68) were included. Median PSA level and prostate volume were 9.5 $\mu\text{g/l}$ (6-15) and 40 ml (32-54), respectively. At preoperative staging, unilateral mpMRI stage $\geq T3a$ was found in 54 (58%) and highest ISUP 4-5 in 37 men (40%). On the contralateral side, 21 (23%) and 23 men (25%) had ISUP grade 1 and 2-3, respectively. 24 men (26%) underwent open and 69 men (74%) robot-assisted laparoscopic RP. Bilateral, contralateral or no NS was performed in 34 (37%), 46 (49%), and 13 men (14%), respectively. Side-specific analysis on the final pathology showed ISUP grade group 4-5 in 25 men (27%) on the preoperative high-risk side and in 18 men (19%) contralaterally. ECE and SVI on the high-risk side was confirmed at RP in 45 (48%) and 16 men (17%) respectively; only in 10 (11%) and 10 men (11%) in the contralateral side. PM were reported in 34 men (37%) in the high-risk side and in 14 men in the contralateral side (15%). The only relevant independent predictor of contralateral ECE was contralateral ISUP grade (OR 2.3; 95% CI 1.2-4.5; $p = 0.012$).

CONCLUSION:

As only one in ten men has ECE in the non-dominant side, a "one-fits-all" approach with wide excision seems not justified. ISUP grade in the non-dominant side might inform when to perform or not to perform NS-RP.

P09 “It’s not the radiologist’s fault”: Positive surgical margins at robot-assisted radical prostatectomy occur on the main tumor revealed by MRI and biopsies.

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Objectives

A positive surgical margin is a well-known risk factor for biochemical recurrence following radical prostatectomy (RP). With the advent of preoperative MRIs and image guided-biopsies, prostatic locations at risk of resulting in a positive margin are carefully studied before RP. In the context of a general downward trend in margin rates in our institution, we hypothesized that the remaining margins occur in regions of the prostate thought not to contain cancer. We therefore confronted preoperative MRI and biopsies with margin locations on RP specimens.

Material and methods

Patients were identified from the prospectively held RP database within the institution’s certified prostate cancer center. The database includes standardized pathologic and radiologic data. All RPs performed between 2006 and Feb. 2020 by three surgeons (CI, JS, GW) were included. Specimens were examined by dedicated uro-pathologists on whole-mount sections. Tumor locations reported on MRIs and on biopsy reports were confronted with margin location on the specimen.

Results

167 positive margins were found in 151 R1 specimens, of which 14 (9%) were multifocal. Pathological stages were pT2 in 69 (41%) and pT3 in 97 cases (58%). Nerve-sparing surgery was not significantly associated with a positive margin. Margin rates progressively decreased over the study period to reach 5% (pT2) and 21% (pT3) between 2018 and 2020. Main margin location was the apex (53%). Multifocal tumors were observed in 88 specimens (58%). Here, margins were typically located on the index lesion (76%). Preoperative imaging and biopsies suggested the presence of cancer on the margin site in the majority of cases (n=130, 78% and n=124, 74%, respectively). Only 15 margin locations were not known to contain tumor on both preoperative exams (9%).

Conclusion

Contrary to our assumption, positive surgical margins in the age of MRI-fusion biopsies still predominantly occur on the main cancer location shown on preoperative workup. Less than 10% of positive margins are located in supposedly “falsely reassuring” zones. These findings suggest that

- positive surgical margins rather stem from shortcomings in surgical technique than planning.
- further integrating imaging into the technique can improve cancer control.

P10 Dynamic Contrast Enhancement in Prostate MRI as Predictor of Erectile Function and Recovery after Radical Prostatectomy

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Background:

Our aim was to analyze routine preoperative dynamic contrast-enhanced (CE) multiparametric magnetic resonance imaging (mpMRI) of the prostate, to predict erectile function (EF) before and after radical prostatectomy (RP).

Methods:

Patients who underwent RP between 01/2015 and 12/2018 with an existing preoperative mpMRI including dynamic CE images and completed International Index of Erectile Function (IIEF-5) questionnaires at baseline and 12 months were included. They were divided into four erectile dysfunction (ED) groups according to preoperative IIEF-5 score (“no”=25-22 points, “mild”=21-17, “moderate”=16-12 and “severe”=11-5). The perfusion quality in the peripheral zone of the prostate was measured by the ratio of signal increase 120 seconds after wash-in of the contrast agent (Ratio120) in preoperative mpMRI and compared between the groups.

Results:

Ninety-seven patients met the inclusion criteria. The Ratio120 showed statistically significant differences among all of the preoperative ED groups ($p=0.020$). For postoperative prediction, 43 patients were dichotomized into “no-mild” (≥ 17 points) and “moderate-severe” (≤ 16) ED groups according to IIEF-5 scores at 12 months postoperative. The Ratio120 revealed significant differences among the postoperative ED groups (128.84% vs. 101.95%; $p=0.029$). The multivariable regression analysis demonstrated consistent results for Ratio120 after adjusting for age, nerve-sparing and preoperative IIEF-5 scores. Further, receiver operating characteristic (ROC) curves demonstrate the additional benefit of measuring the Ratio120 in a diagnostic model.

Conclusions:

Preoperative dynamic CE mpMRI of the prostate may be used for the prediction of EF and postsurgical recovery after RP. This may serve as an important tool in preoperative patient counseling to manage expectations adequately.

P11 Artemis Fusionsbiopsie der Prostata – ist sie besser als die konventionelle Biopsie?

M Muny

Artemis Fusionsbiopsie der Prostata – ist sie besser als die konventionelle Biopsie?

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Hintergrund & Ziele:

Die MRI-Untersuchung der Prostata ist aktuell die zuverlässigste Bildgebung, um karzinomsuspekte Veränderungen zu detektieren und exakt zu lokalisieren. Bei der Fusionsbiopsie handelt es sich um eine Weiterentwicklung der bisher empfohlenen standardisierten Ultraschall gesteuerten Prostatabiopsie. Ziel der Studie war die Bewertung der Fusionsbiopsie im Vergleich zur Standardbiopsie im Hinblick auf die Diagnose eines Prostatakarzinoms bei mittlerem bis hohem Risikoprofil.

Patienten und Methoden :

Wir erfassten 541 Männern, die sich von Juli 2017 bis Dezember 2020 im Praxisnetzwerk der Uroviva gleichzeitig einer Fusions- und einer Standardprostatabiopsie unterzogen. Bei der transrektalen Artemis-Fusionsbiopsie werden die MRI-Bilder mit den sonografischen Bildern in Echtzeit kombiniert, sodass die im MRI auffälligen Läsionen auch gezielt punktiert werden können. Die untersuchten Patienten hatten entweder ein erhöhtes PSA und/oder eine PI-RADS Läsion ≥ 3 im MRI.

Resultate:

Es wurden insgesamt 541 Männer im Alter von 65,2 Jahren ($\pm 8,3$) mit einem durchschnittlichen PSA von 8,6 ng / ml ($\pm 8,6$) und einem Prostatavolumen von 55,9 cm³ (± 28) untersucht. Im MRI zeigte sich bei 534 Männern (99 %) eine PI-RADS Läsion ≥ 3 . Bei 386 Männern (71 %) stimmten die Ergebnisse der Fusions- mit der Standardbiopsie überein, wobei sich bei der Standardbiopsie in 48 % und der Fusionsbiopsie in 43 % ein Prostatakarzinom zeigte.

Bei Patienten mit erhöhtem Prostatakarzinomrisiko im MRI konnten mit der Standardmethode 76 % (PI-RADS 5) bzw. 45 % (PI-RADS 4) und der Fusionsbiopsie 78 % (PI-RADS 5) bzw. 41 % (PI-RADS 4) ein Prostatakarzinom nachgewiesen werden. Männer mit einer PI-RADS 3 Läsion im MRI zeigten in der Standardbiopsie zu 30 % und bei der fusionierten Methode zu 15 % einen pathologischen Befund.

Schlussfolgerung:

Zusammenfassend waren bei Patienten mit erhöhten Prostatakarzinomrisiko (PI-RADS ≥ 4) die Resultate vergleichbar (215 gegenüber 227 Fälle), während bei Niedrigrisikopatienten (PI-RADS ≤ 3) in der Fusionsbiopsie sogar weniger Tumore nachgewiesen werden konnten. Weitere Studien werden erforderlich sein, um letztendlich die Bedeutung einer gezielten Biopsie besser beurteilen zu können.

P12 MRI compared to DRE staging for prostate cancer: a Will Rogers phenomenon

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Aim and objectives

Risk stratification groups were developed and validated using staging based on DRE. It may be inappropriate to apply MRI staging to these risk stratification systems because non-palpable disease, MRI visible lesions may be reclassified from a group with classically favorable outcomes to a less favorable group. We aimed to test whether this re-classification and apparent improvement in outcomes of both groups might lead to the so-called Will-Rogers phenomenon in men following radical prostatectomy.

Methods

A retrospective study of 572 consecutive patients undergoing laparoscopic radical prostatectomy at a single institution (2007–2017) with complete pre-operative staging data. Clinical stage was recorded by the operating surgeon whilst MRI and pathological stage were recorded after tumor board review. Progression-free survival was defined as absence of any rising PSA, no adjuvant/salvage treatment, and no metastases or mortality. PFS was compared between D'Amico risk groups using either clinical or radiological stage.

Results

Median age was 63 years (IQR 58.5–67) and median PSA was 8.9 ng/ml (IQR 6.5–13.2). 20% were D'Amico low risk, while 43% were medium and 37% high risk using DRE as the local staging method. The median follow-up time was 23 months (IQR 22-73). DRE stage was available for all patients, while MRI staging was available for 60% (n = 342). PFS was seen in 61% (348/572). The median time to failure by PFS composite outcome was 9 months (IQR 5 - 54).

When comparing same stage groups, those classified using mpMRI showed improved PFS on Kaplan-Meier curves compared to the same stage classified by DRE. However, the difference was only significant in the T1 and T3 groups. Univariable analysis showed that patients with DRE T1 disease (HR 0.10 95%, CI 0.01-0.73, p = 0.02) or DRE T3 (HR 0.70, CI 0.51-0.97, p = 0.03) were at higher risk for failure. Multivariable analysis was performed in a subgroup fashion, comparing corresponding DRE and MRI stages corrected for age, grade group and PSA. Only DRE T1 remained a significant predictor for worse outcome (HR 0.08, CI 0.01-0.59, p = 0.01).

Conclusion

Our results suggest that stage classified by MRI rather than DRE leads to a possible Will Rogers phenomenon. Current risk groups were developed and validated on clinical stage and should be used with caution when counseling patients in whom local stage is often based on mpMRI. A recalibration of our risk tools based on imaging is required.

P13 The future of prostate cancer screening - How Artificial Intelligence predicts Clinically Significant Prostate Cancer"

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Background and aims:

Multi-parametric magnetic resonance imaging in combination with MRI targeted biopsies have become the gold standard in prostate cancer diagnostic. However, it remains a clinical challenge to distinguish the presence of clinically relevant tumors from ones that may never have become evident. The incorporation of artificial intelligence (AI) into imaging processes and imaging interpretation represents a potential solution for this task. Therefore, we investigated the performance of supervised machine learning techniques to predict clinically relevant cancer from quantitative image-features and compared it to the results of established PIRADS v2 assessment scores.

Material and Methods:

We retrospectively included 201, histopathologically-proven, peripheral zone prostate cancer lesions. Gleason scores $\leq 3 + 3$ were considered as not clinically relevant and Gleason scores $\geq 3 + 4$ as clinically relevant and were encoded in a binary fashion, serving as ground-truth. MRI was performed at 3T with DCE using golden-angle radial sparse (GRASP) MRI. Perfusion maps (Ktrans, Kep, Ve), apparent diffusion coefficient (ADC), and absolute T2-signal intensities were determined in all lesions and served as input parameters for four supervised machine learning (ML) models: Gradient Boosting Machines (GBM), Neural Networks (NNet), Random Forest (RF) and Support Vector Machines (SVM). ML results and PI-RADS scores were compared with the ground-truth, ROC-curves and AUC values were then calculated.

Results:

All ML models outperformed PI-RADS v2 assessment scores in the prediction of clinically relevant prostate cancer (RF, GBM, NNet and SVM vs PI-RADS: AUC 0.899, 0.864, 0.884 and 0.874 vs. 0.595, all $p < 0.001$).

Conclusions:

This work highlights the potential of AI to further improve the prediction accuracy of imaging techniques in prostate cancer diagnostics. These findings represent prerequisites for future precision diagnostics, in which supervised machine learning techniques can help to reduce the number of significant cancers missed and insignificant cancers detected.

P14 Novel urine biomarkers for the early detection of prostate cancer

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Introduction:

Prostate cancer (PCa) is the fourth most common cancer worldwide, accounting for 15% of all cancers [1]. The current standard for the screening of PCa is based on the blood levels of the prostate specific antigen (PSA), whose main shortcomings are the high rate of false positives. In fact, 40-50% of men undergoing prostate biopsy turn out to be tumor free [2]. Thus, the current screening procedure unnecessarily subjects a relevant number of patients to considerable side-effects, such as infections and bleeding. In our previous study we evaluated a first urine test based on the biomarker IDO to refine the early and non-invasive detection of PCa [3]. To further improve specific test strategies complementing PSA, additional biomarkers are urgently needed.

Materials and methods:

Urine samples from men with elevated levels of PSA were collected before prostate biopsy. A mass-spectrometry (MS) screening was performed on a cohort of 45 samples to identify new biomarkers that showed a significantly different distribution in tumors ($p < 0.05$).

Validation of the candidate biomarkers by ELISA is on-going.

Results: Eight biomarkers (undisclosed due to patent claims) were either significantly under- or over- expressed in men with prostate tumors as compared to controls. Each single biomarker showed a sensitivity of 100% and, by combining all true negatives of each biomarker, the overall specificity reached 90%. The validation by ELISA is on-going and the preliminary data, performed on the same cohort as for MS, show that the quantification of biomarker 1 combined with two control proteins reaches a sensitivity of 100% and specificity of 76%.

Discussion:

With this study, we aim at developing a multi-plex immunoassay based on urine analysis, targeting a panel of novel biomarkers that can predict the presence of a prostate tumor with a sensitivity $> 99\%$ and a specificity $> 50\%$. Through a MS screening, we have identified eight novel candidate and six control molecules that can complement our previously discovered biomarker IDO, by increasing the specificity of the test while maintaining an extremely high sensitivity (current sensitivity 100% and specificity 76-90%), independently of age and other clinical variables. The clinical implementation of a test with such performances would result in the marked reduction in the number of unnecessary biopsies and subsequent complications, thereby improving the quality of life of patients and reducing healthcare costs.

P15 Open transvesical simple prostatectomy: long-term outcomes from a Swiss university hospital and teaching center.

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Objective

The open transvesical simple prostatectomy (OTSP) is a surgical procedure used for more than a hundred years with a known high complication rate. The aim of this study is to review our perioperative, short and long-term outcome.

Methods

We reviewed file of all OTSP operated patient from 2013 until March 2020. Classic demographics parameters were recorded as well as preoperative parameters (PSA, prostate volume, Qmax, PVR, IPSS), perioperative parameters (length of surgery, length of stay, complication according to Clavien-Dindo, pathology) medium term and long term outcome (Qmax, IPSS, PVR, late complications). When necessary, values are given as medians or proportions.

Results

140 patients underwent simple prostatectomy. Pre-operative characteristics were: age 70 years, ASA 2, BMI 27, PSA: 7.7ug/l, prostate volume 109cc (values are medians). 7% were under antiplatelet therapy, 4% under anticoagulants and 55% were under 5 α -reductase inhibitor. Preoperative functional parameters were: median Qmax 7.3ml/s (IC 2-14; N=52); median PVR 54ml (IC 0-300; N=58); median IPSS 16 (IC 9-27; N=25). Median operating time was 160 min (IC 102-258), and length of stay 7 days (IC 5-15). Complications above Clavien 1 occurred in 20% (IC 15-30), no death occurred. Transfusion rate was 10% (IC 5-16), revision surgery rate 9% (IC 5%-14), readmission rate 3% (IC 1-7). Functional outcome before 3 month: median Qmax: 20ml/s (IC 9-43; N=73); median PVR 10ml (IC 0-70; N=101); median IPSS score: 5 (IC 0-11; N= 17). Incontinence was reported in 24% (IC 18-32; N=135) before postoperative month 3, in 7% (IC 3-12;N=134) between month 3 and 6 and in 4% (IC 2-8; N=133) at the end of the follow-up. One patient required artificial sphincter placement. The remaining 4 patients had urge incontinence. Late complications were bladder neck sclerosis, urethral stenosis, incisional hernia in 7% (IC 3-12;N=139). Bladder neck sclerosis required endoscopic revision in all of the 2 patients, with one requiring open revision. Urethral stenosis required meatotomy in 4 out 7 with no need to further procedure, one required intermittent urethral dilatation, the two remaining refused treatment.

P16 Water vapor thermal therapy as treatment option for benign prostatic hyperplasia related lower urinary tract symptoms - first experience and results in a swiss single-center

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Introduction:

Rezüm as a treatment method with water vapor thermal therapy for benign prostate hyperplasia (BPH) related lower urinary tract symptoms (LUTS) has evolved significantly during the last 5 years. Recent data from multicenter trials and registries are reporting promising results. Our objective is to present our first experiences and results with rezüm.

Methods:

Retrospective single-center analysis of patients treated with rezüm at the University Hospital Basel between May 2014 and February 2020. Using a rigid cystoscopy, water steam was transferred by a single-use delivery device. Steam was injected in 9-seconds bursts into the transitional zone to the lateral lobes of the prostate, if needed into the midlobe, with a needle emerging out of the delivery device. Due to postoperative prostate edema and expectable worsening of the LUTS a transurethral catheter was inserted intraoperatively in all patients. Intra- and postoperative data are shown as median with interquartile range. As data are still being collected, longterm results will be presented during the congress.

Results:

Rezüm was performed in 72 patients, in 9 patients in local anesthesia, in 33 patients in analgosedation only, in 7 patients in spinal anesthesia and in 23 patients under general anesthesia. Preoperative prostate volume was 45 ml (35–71). 17 patients (24%) had an indwelling catheter by the operation date. In total 6 injections (4–8) were given during the procedure, 4 to the lateral lobes (4–6) and 1 (0–1) into the midlobe. Midlobe treatment was performed in 35 patients (49%). Operation time was 11 min (9–17). 25 patients (35%) were treated on an outpatient basis. Hospitalization was 2 days (1–3) in 47 patients (65%). Indwelling catheter was removed after 5 days (4–6). In 13 patients (18%) re-catheterization was necessary. Second catheter removal after a median 21 days (10–37) was successful in another 7 patients (10%). After a median 48 days (39–69) prostate volume diminished to a median size of 28 ml (- 38%). IPSS improved from a median 17 (12-20) to 7 (5-14) (- 59%) resulting in an improvement of QoL from 3 (3-4) to 1 (1-2) (- 67%). Maximal urinary flow rate increased from 10 (6-13) to 13 (10-15) ml/sec (+ 30%). 30-days Clavien-Dindo grade IIIa complication rate was 2.7%.

Conclusion:

Our results confirm published data about rezüm being a safe and quick to perform procedure under general anesthesia-free conditions, providing early relief from BPH related LUTS.

P17 REZUM Water Vapor Therapy under intravenous sedation: 1-year experience at the University Hospital Zurich

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Introduction

REZUM Water Vapor Therapy has recently become available in Switzerland. This study evaluates efficacy and safety of this therapy 1 year after its introduction at the University Hospital Zurich.

Methods

All patients undergoing REZUM therapy since June 2019 were included. All patients underwent surgery under intravenous sedation and antibiotic prophylaxis. Procedures were performed according to manufacturer's instructions and included a 2 minutes intraurethral lidocaine-gel application. Medical charts were reviewed for data extraction. Primary outcome was time to catheter withdrawal. Secondary outcomes were anesthesia-related complications, hospital stay length, continuous bladder irrigation (CBI) >24h and postoperative urinary tract infection (UTI) within 1 month after surgery, as well as maximal urinary flow (Qmax), post-void residual volume (PVR) and continence at 3 months after surgery.

Results

At total of 21 patients were available for analysis. Median age was 76 years (range 57 – 91). ASA-score was ≥ 3 in 15/21 (71 %) patients. Before surgery, 6/21 (29 %) patients had a permanent indwelling catheter. Median prostate volume was 44 ml (range 31 – 105). Median operative time was 8 minutes (range 4 – 27). A median 5 water vapor injections (range 4 – 10) were applied. Prostate volume significantly correlated with injections count ($R^2 = 0.46$; $p < 0.01$), but not with operative time ($R^2 = 0.02$; $p = 0.54$). Postoperative delirium occurred in 1 patient (5 %). Median hospital stay was 1 day (range 1 – 6). CBI >24h was necessary in 2 (10 %) patients. UTI occurred in 2 (10 %) patients. Median time to catheter withdrawal was 9 days (range 5 – 50). All patients were catheter-free within 50 days. Significant improvement of Qmax (median 7 ml/s higher; $p = 0.02$) and PVR (median 27 ml lower; $p < 0.01$) was found, and continence was preserved in all patients.

Conclusions

REZUM water vapor therapy under intravenous sedation is applicable to patients with severe comorbidities. Continent spontaneous voiding is granted within 2 months after surgery. Complications such as postoperative delirium, significant hematuria or UTI occur seldom, but require close monitoring of patients after surgery.

P18 Publication Patterns in Urology During the Last Decade: Do Editorial Board Affiliations, Gender and the Geographical Location of the Corresponding Author Influence the Scientific Interest?

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Purpose:

It was our aim to investigate publication patterns among the the three highest-ranked urology journals of Europe and Northern America during the last decade. Specifically, our aim was to evaluate if editorial board affiliations, gender and the geographical location of the corresponding author influence the scientific interest.

Methods:

We used Web of Science to obtain all available meta-data of publications in the three highest-ranked urology journals of Europe and Northern America during the last decade. We derived the citation count of each publication (standardized to month of publication) to measure overall scientific interest. Editorial board affiliations were obtained from the editorial offices while gender and geolocation were ascertained by validated algorithms.

Results:

We identified 9286 publications. The mean number of authors per publication was 8.58. Over a quarter (25.9%) of all accepted manuscripts had at least one EBM among the list of authors, more than half of which (13.1%) were positioned either as first or last author. A higher standardized citation count was positively correlated with the proportion of EBM among the list of authors ($r = 0.061$, 95% CI: 0.041 to 0.081, $p < 0.001$). Female authors were listed among the authors in 69.8% of all published manuscripts. However, females were only seen in 27.1% at the first or last authorship position. The standardized citation count was negatively correlated with the proportion of female authors ($r = -0.053$, 95% CI: -0.073 to -0.033, $p < 0.001$). Geographical heatmaps demonstrated that regions of submission were evenly distributed to Europe, North East America and far-eastern Asia regardless of the journal.

Conclusion:

Scientific interest of articles published in the three most influential urological journals positively correlates with EBM among the authors. Female scientists are underrepresented and therefore contribute less to publications in high-impact journals than males.

Posterdiskussion II – Blasenkarzinom

Discussion des posters II – Carcinom de la vessie

P19 Enhanced recovery after surgery (ERAS) for radical cystectomy in 2020: to improve is to change.

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Introduction & objectives

Enhanced recovery after surgery (ERAS) was developed to reduce surgical stress and prevent postoperative complications. Since 2013, the protocol has continuously evolved: considerable efforts have been made to improve patient's autonomy in order to promote early mobilization and recovery. The aim of our study was to evaluate the impact of the recent changes of our ERAS protocol on radical cystectomies (RC) patients.

Methods

Since 2012, all patients who undergo elective RC with urinary diversion follow a dedicated ERAS protocol, which is constantly updated. Three main modifications were analyzed: postoperative wearing of personal clothes (PC; 2019), postoperative analgic treatment with continuous wound infiltration using peri-incisional catheters (PACI; 2017) and p.o. Rivaroxaban antithrombotic prophylaxis (AP; 2019). Patients were instructed to use PC starting at postoperative day 3. PACI consists of a slow infusion of 0.2 % Ropivacaine for 72 hours. As AP, 10mg Rivaroxaban p.o. is prescribed at the time of discharge until 4 weeks after surgery instead of fractionated heparin.

Results

Since June 2019, 26 patients started using PC after RC instead of standard hospital gown. All of them received also PACI with no need of epidural anesthesia. Their median length of stay (LOS) was 12 days (IQR: 9-15) compared to 14 days (IQR: 10-16) for the group with only PACI and no-PC (n=26) and 18 days (IQR 14-26) for those followed with the initial ERAS protocol (epidural and no-PC; n=52) (p=0.06). No increased complication or readmission rates were reported in the PC group. Demographic and oncological data were comparable among all of three groups. On univariable analysis, PACI and PC wearing were found significantly associated with a shorter LOS, while on multivariable analysis only PACI was an independent predictor of reduced LOS. No significant shorter bowel recovery was found among PACI patients regardless of clothing status. However, PACI patients could significantly faster tolerate solid food intake than those with the epidural anesthesia (5 days versus 11 days, respectively; p = 0.001). No deep venous thrombosis or bleeding were reported at 30-days when Rivaroxaban was prescribed.

Conclusions

Encouraging patients to get dressed with their PC after RC rather than with a hospital uniform may reduce LOS. This effect tends to be even more prominent when associated with PACI as pain management strategy. Rivaroxaban seems to be a valid AP

20 Impact of the ERAS® protocol compliance on bowel recovery, complications and length of stay after radical cystectomy for bladder cancer

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Introduction & Objectives

Despite standardized surgical technique and the development of new perioperative care protocols, radical cystectomy (RC) morbidity remains a serious challenge for urologists. Postoperative ileus (POI) is one of the most common postoperative complication, often leading to longer length of stay (LOS). Enhanced Recovery After Surgery (ERAS®) pathway was built to decrease surgical stress and therefore reduce surgical complications and LOS. The aim of our study was to assess the impact of the compliance to the ERAS® protocol on bowel recovery, 30-day complications and LOS after RC for bladder cancer (BC).

Methods

Data from consecutive patients undergoing RC for BC within an ERAS® dedicated protocol were analyzed. Exclusion criteria were urinary diversion other than ileal conduit and palliative RC. ERAS compliance was defined according to the prospective ERAS® Interactive Audit System. Patients were divided into 2 groups according to their compliance (A: low-compliance and B: high-compliance). Postoperative complications were prospectively recorded by a dedicated study nurse at 30 days after RC. POI was defined as the placement of a nasogastric tube. Logistic regression analysis was used to identify predictors of 30-day complications and POI.

Results

After considering the exclusion criteria, 108 patients were included for the final analysis. Median global compliance to the ERAS® protocol was 61%. 78 (72%) patients had a compliance < 65% (group A), while the remaining 30 (28 %) a compliance > 65% (group B). The two groups were similar in term of age, gender, smoking status, tumor stage and readmission or reoperation rates. No significant differences were found regarding 30-days complication rate (86% in group A versus 73% in group B, $p = 0.82$) and the LOS (14 days in group A versus 15 days in group B, $p = 0.82$). Time to stool was significantly shorter in group B (4 days versus 6 days, $p = 0.02$) and time to tolerate solid food was slightly faster in group B but not significant (8 versus 7 days, $p = 0.23$). On multivariate analysis, ERAS® compliance was not significantly associated with 30-days total complications. However, a lower compliance to the ERAS® protocol and the age > 75 years were significant independent predictors of a higher risk of POI.

Conclusion

Higher compliance to the ERAS® protocol seems to improve bowel recovery and prevent POI after RC. However, it may not decrease 30-day complications and LOS after RC.

P21 The impact of preoperative nutritional status on post-surgical complication and mortality rates: a review for patients treated with radical cystectomy

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Background:

Radical cystectomy (RC) with bilateral pelvic lymph node dissection is the standard of care in the treatment of muscle-invasive or high risk non-muscle-invasive bladder cancer. Despite advances in surgical techniques and perioperative care pathways, post-surgical complication rates remains high and postoperative survival outcomes persist suboptimal.

Objective:

To test the impact of preoperative nutritional factors (body mass index [BMI], serum albumin level and sarcopenia) on post-surgical (30-day and 90-day) complication and mortality rates after RC.

Materials and methods:

A systematic review of studies that investigated the impact of nutritional status on postoperative outcomes after RC was performed using PubMed database. English-language articles published from 1st March 2010 to 1st March 2020 were reviewed. The papers selection has been done according to the PRISMA guidelines.

Results:

Overall, we collected 81 studies, including 4 prospective and 77 retrospective. 29 of these works were included in the final analyses. Patients with a BMI between 25 and 29.9 kg/m² and those with a BMI \geq 30 kg/m² had a 1.5-fold (odds ratio [OR] 1.55, 95% confidence interval [CI] 1.14 – 2.07) and an almost 2-fold (OR 1.73 95% CI 1.29 – 2.40) increased risk of 30-day complications after RC, respectively. In our work preoperative hypoalbuminemia (< 3.5 g/dL) increased the risk of 30-day complications (OR 1.56, 95% CI 1.07 – 2.35). This factor proved also to be a strong predictor of worse 3-years overall survival (OS) (hazard ratio [HR] 1.86, 95% CI 1.32 – 2.66). Sarcopenic patients, identified with skeletal muscle index (SMI), were 2.5 times more at risk of complications within 90 days after RC than non-sarcopenic ones (OR 2.49, 95% CI 1.22 – 5.04). Sarcopenia resulted, moreover, a good predictor of unfavourable 5-years cancer-specific survival (HR 1.73, 95% CI 1.07 – 2.80) and OS (HR 1.60, 95% CI 1.13 – 2.25), while the impact on short-term mortality rates has still been little investigated.

Conclusions:

High BMI, hypoalbuminemia and sarcopenic status were associated to an increased risk of post-surgical complications and the latter two also proved to be good predictors of long-term mortality. Preoperative assessment of nutritional status of patients undergoing RC is therefore an useful tool to predict post-operative outcomes and should be routinely included in clinical practice after further investigation through prospective studies.

P22 Comparison of peri-operative and mid-term oncologic outcomes of robotic versus open radical cystectomy

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Robotic cystectomy (RC) has emerged over the last 10 years, although its putative advantages have been thoroughly questioned with respect to the open surgery gold standard. The aim of this study was to compare peri-operative and mid-term oncologic outcomes of RC throughout its initial implementation phase with open radical cystectomy (OC) in a medium size institution.

We included retrospectively 56 patients. RC was performed between 2016 and 2019 by a single surgeon with extensive robotic surgery experience, assisted by a senior staff who contributed to lymphadenectomy. Surgical indication was either oncological or functional. Post-operative complications were reported according to the Clavien classification. Using Stata15, univariable analyses relied on Student's t-test and Chi-squared. Survival analysis was performed with the log-rank test and Cox regression models and visualized according to the Kaplan-Meier method. All statistical tests were two-sided with $p < 0.05$ considered as statistically significant. Values are means \pm SD.

OC was performed in 29 patients (52%) and RC in 27 (48%), with a conversion to open surgery rate of 26%. Of the 56 radical cystectomies, 45 (80%) were performed for oncological indication. Age was 71 ± 8.5 years. Patients and tumor characteristics were similar in the 2 groups, except for BMI score who was significantly higher in the RC group ($p = 0.009$), and previous radiotherapy mostly present in the OC cohort ($p = 0.02$). Ileal conduit was performed 71% of cases, with a significantly higher proportion of neobladders in RC ($p = 0.003$). After excluding the 7 cases converted to OC, operative time was significantly higher in RC (479 ± 99 minutes) than OC (377 ± 19 minutes; $p = 0.001$). Blood loss and need for transfusion were significantly lower in RC (respectively $p = 0.001$ & 0.002). Length of hospitalization was 18 ± 11 days and significantly lower in RC ($p = 0.001$) with 37% of these staying less than 10 days. Rate of early and late post-operative complications were similar in the two groups. After a follow-up of 12 ± 10 months, tumor recurrence was 24% and overall survival 73%, higher in the RC cohort ($p=0.049$). There were no differences in recurrence and cancer specific survival rates.

Although through a learning phase, RC is not inferior to OC regarding peri-operative and oncological outcomes, while offering to a significant number of patients the advantages of minimally invasive surgery.

P 23 Frailty scores comparison to predict short-term morbidity after radical cystectomy

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Context and objectives

Radical cystectomy (RC) for bladder cancer (BC) is a highly morbid surgery with a rate of postoperative complications up to 70% at 30 days. A dedicated Enhanced Recovery After Surgery (ERAS[®]) protocol for RC was built to reduce surgical stress in order to decrease morbidity. However, despite these efforts, frail patients are often advised against RC. The aim of this study was to identify the most reliable frailty score to predict complications after RC and to evaluate whether the ERAS[®] protocol is feasible among frail patients

Material and methods

Data from 183 patients treated with RC for BC were analyzed. After exclusion of palliative RC (n = 19) and patients with a urinary diversion other than incontinent ileal conduit (n = 27), 137 patients were considered for analysis and divided into 2 groups according to their frailty status. Frailty was defined using 3 validated scores: the American Society Anesthesiologists (ASA) score ("frail" if ASA \geq 3), the Charlson Comorbidity index (CCI) ("frail" if CCI \geq 7) and the simplified 5-items Frailty index (sFIFI) ("frail" if sFIFI \geq 2), which included hypertension, diabetes, chronic obstructive pulmonary disease, congestive heart failure and WHO performance status. Logistic regression analysis was used to identify predictors of any 30-days complications. The accuracy of the scores was measured by the area under the curve (AUC).

Results

Of the 137 patients, 108 (78%) followed a dedicated ERAS[®] protocol. Risk-stratification according to the frailty scores revealed no significant difference regarding age, tumor stage, readmission rate and the compliance to the ERAS protocol. Only frail patients according to the ASA score, had a higher rate of 30-days complications (p = 0.02) and a longer length of stay (p = 0.001), whereas the other scores did not show any difference. On univariable analysis, frailty according to the ASA score, longer surgical time and low ERAS compliance were found significantly associated with morbidity, while only ASA score and length of surgery independent predictors of complications. By adding the ASA score to the base model, the accuracy in predicting 30-days complications improved by 7.6% (AUC 74.3%), while only by 0.2% and 1.6% when the sFIFI and the CCI were added, respectively

Conclusion

The ASA score seems to be the most reliable frailty tool to predict complications after RC for BC. Adherence to ERAS[®] protocol seems to decrease early morbidity, also in frail patients

P24 Outcomes of radio-frequency induced thermochemotherapy for the treatment of non-muscle invasive bladder cancer in a Swiss tertiary care center

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Aim

To review the outcomes of radio-frequency induced thermochemotherapy (RITE) for the treatment of intermediate and high-risk, non-muscle invasive bladder cancer (NMIBC) in our institution.

Patients and methods

Analysis of all patients having undergone RITE at Geneva University Hospital since January 2017. All patients underwent TURBT and upper urinary tract imaging (CT or MRI) at least 6 months before treatment. Follow-up was performed according to EAU guidelines.

Results

Twenty-one patients underwent treatment since Jan. 2017, 19 men and two women. Mean age was 70. 14 patients with indication for radical treatment refused or were unfit for cystectomy. Previous adjuvant treatments before NMIBC recurrence were instillation therapies with BCG (14), cytotoxic agents (2), cytotoxic agents and BCG (2) or hyperthermal MMC and BCG (1). Two had not undergone any other type of treatment.

Indications were adjuvant treatment (10) CIS (9) or chemo-ablation (2). Used protocols were identical regardless of indication.

Generally treatment was well tolerated, with 13 reporting no toxicity.

18 patients completed induction. Three patients did not complete induction and were lost to follow-up. Overall, six interrupted treatment due to intolerance: three during induction, two before starting maintenance, one during maintenance. Reasons were incapacitating irritative symptoms (2), allergy (1), UTI (1), refusal (1), perineal pain (1).

Of 18 patients completing induction, 12 stayed recurrence-free with a median follow-up of 16 months, four recurred: two after induction, one at 16 and one at 22 months. Recurrences were, two pTaG3, two pT1 and one pTa G1.

Conclusion

In a population of patients with intermediate and high-risk NMIBC, mostly unfit or refusing cystectomy, the majority was able to complete induction. More than half stayed recurrence free after a median follow-up of 16 months. RITE is a treatment option in selected patients with intermediate and high-risk NMIBC. Of note, other treatment modalities for this disease are being evaluated in clinical trials in Switzerland.

P25 En bloc resection (ERBT) of non muscle invasive bladder cancer. Hope or hype?

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The inherent limitations of conventional transurethral resection of bladder tumors (TURBt) as the standard approach for diagnosis and treatment of bladder cancer are well known: staging error caused by insufficient assessment of resection depth as well as intravesical tumor fragmentation that complicates histopathological evaluation. The purpose of this presentation is to present the various technical approaches and novel recent clinical data, as well as data of meta-analysis on en bloc resection of bladder tumor (ERBT) that has been demonstrated to offer high potential to overcome these limitations.

Recent findings

All recently published studies confirm the results of the EBRUC trial from 2015 for laser ERBT and current-based ERBT. ERBT provides a better resection quality with up to 95% presence lamina muscularis propria as surrogate marker for quality. It can be performed using all energy sources. Available data demonstrate with all due limitations of reporting quality no relevant difference with regard to perioperative morbidity compared with conventional transurethral resection of bladder tumors. No conclusions can be drawn regarding the impact of ERBT on recurrence as data are still controversial. Several ongoing multicenter trials are currently taking place to address this issue.

Summary

ERBT has gained momentum in the past years. The hypothesized advantages over conventional TURBT seem to manifestate for tumors up to 3 or 4 cm in size with regard to staging, specimen quality, and analyzability in pathological evaluation in general. The impact on recurrence remains to be defined by further studies.

P26 Antibiotic prophylaxis for postoperative urinary tract infections in transurethral resection of bladder tumours: a systematic review and meta-analysis.

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Background:

Controversy exists regarding the necessity of antibiotic prophylaxis (AMP) for postoperative urinary tract infections (UTIs) after transurethral resection of bladder tumours (TURB). This potentially leads to overuse of AMP, causing side-effects and rising antimicrobial resistance rates.

Objectives:

To systematically review relevant literature (i) comparing the impact of different AMP schemes versus no AMP on postoperative UTI and (ii) to assess risk factors for UTI after TURB.

Methods:

Up to April 3, 2019 we conducted (i) a systematic search to collect evidence from randomised control trials (RCTs) and non-randomised studies on any form of AMP use in patients with TURB and (ii) a scoping search to identify risk factors for UTI after TURB. A meta-analysis (i) was carried out to assess the impact of AMP use on postoperative UTI and on asymptomatic bacteriuria (ABU). The risk factors identified in the scoping search (ii) were collected in a descriptive summary of evidence table.

Results:

The literature search (i) identified 1,268 potential titles and abstracts. Seven studies, recruiting 1,725 patients, were included. Overall, no significant effect of AMP on UTI was found: The pooled odds ratio (OR) of the fixed effect model was 1.36 (95% confidence interval [CI] 0.75-2.44), and from the random effects model 1.52 (95% CI 0.74-3.12). The observed between-study-heterogeneity was low ($Q = 5.44$, $p = 0.36$). None of the tested variables (i.e. study design, exclusion of pre-operative UTI, publication year and sample size) seemed to explain the between-study-heterogeneity. It seemed that AMP reduces the “risk” (OR) of an ABU after TURB compared to placebo (OR 0.45 [0.25 - 0.82]). To assess risk factors for UTI following TURB (ii), 1,487 reports were identified and three studies were included. Evidence on risk factors was low and heterogenous. Age, preoperative pelvic radiation, preoperative hospital stay, duration of operation and tumour size as well as preoperative bacteriuria and pyuria seem to be associated with postoperative UTIs.

Conclusions:

Moderately strong evidence exists, that AMP in patients undergoing TURB does not reduce postoperative symptomatic UTIs even though AMPs have a small benefit to reduce asymptomatic ABU. Assessment of risk factors for UTIs is heterogeneous and further work is required to determine if a sub-group of patients might benefit from AMP.

P27 Outcomes and technique for extraperitoneal robotic YV-plasty for recurrent bladder neck stenosis

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Introduction and Objective

To demonstrate the outcomes and the technique of robot assisted Y-V (RAYV) plasty bladder neck reconstruction with preferable extraperitoneal approach for recurrent bladder neck stenosis (BNS).

Methods

We present our results and the technique of 22 patients who underwent RAYV March 2016 to July 2019 in our department. 22 cases of BNS emerged after transurethral resection of the prostate. The indications were residual volume, dysuria and attenuated urinary stream. Following an extraperitoneal approach with a three arm Da Vinci Si system, the perivesical space is cleaned. The bladder neck is located and the ventral part of the prostate is exposed. An anterior longitudinal incision is performed starting from the bladder neck over the ventral vesico-prostatic junction down through the stenotic area to the external sphincter. The incision is enlarged to an inverted Y-shaped opening and an indwelling catheter is inserted. The tip of the V-shaped bladder flap is brought to the base of the inverted Y and closed with a running barbed suture.

Results

22 patients with BNS underwent RAYV (table 1). All patients had undergone at least 2 transurethral procedures for the initial treatment. No conversion to open surgery had to be performed. The median operative time (skin to skin) was 133 min (range 69-180), the estimated blood loss was median of 5 (range 0-200) ml. There were no intraoperative and four patients with Clavien Dindo III as postoperative complications. The transurethral indwelling catheter was removed after 8 (4-25) days. The hospitalization period was median 5 (3-14) days, as patients preferred to leave the hospital without an indwelling catheter. Most of the patients showed six weeks postoperative a significant improvement of dysuria and residual volume as well as an increasing uroflowmetry (table 2). There was no recurrence of BNS with a median follow-up of 19.4 (2-42) months.

Conclusion

The extraperitoneal robotic YV-plasty is a feasible and minimally invasive approach for recurrent bladder neck stenosis. Still, long-term results must confirm the efficacy in the future.

P28 Small Cell Carcinoma of the Urinary Bladder: is multimodal approach the best treatment option? A Systematic Review

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Background and Objectives

Among bladder cancer histological types, small cell carcinoma (SCCUB) is a rare but highly morbid disease, often associated with a poor prognosis [1,2,3,4]. Therapeutic strategies are extrapolated from those of non small cell lung carcinoma and non small cell bladder carcinoma. The purpose of this paper is to systematically review the existing literature on treatment disease control outcomes, according to the PRISMA criteria.

Materials and Methods

We searched through eligible publications up to April 2020 in Medline, Scopus and reference lists of previous reviews. Two authors independently applied the study criteria, extracted data and assessed methodological quality of studies. We included all epidemiological studies, prospective and retrospective, that investigated diagnosis, treatment options and outcomes for SCCUB and summarised results accordingly.

Evidence Synthesis and Conclusions

A total of 1142 cases across 38 studies have been reported to date, the first case in 1981 [5]. All but one study were retrospective and standards of reporting varied. Most publications consist of case reports, and 31 retrospective studies of variable size were included. SCCUB is a rare, poorly differentiated neuroendocrine epithelial tumor, more aggressive than transitional cell carcinoma (TCC) and with a worse prognosis [1]. The most common symptom at presentation is hematuria. The median OS is 20.7 months [2,8]. Cytology and immunohistochemistry show unique traits. SCCUB can present in pure or mixed forms, with variable expressions of neuroendocrine, epithelial and genetic markers [3,6,7,8]. Due to its rarity, there is no standardised treatment algorithm for SCCUB. In general, the treatment is modelled in analogy to small cell lung carcinoma (SCLC) and TCC. Early studies show that most patients underwent radical cystectomy independently from stage of the disease, while the recent evidence points towards a multimodal treatment modelled on urothelial carcinoma in stages I, II and III, reserving palliative chemotherapy to metastatic disease, with a decrease in radiotherapeutic treatment [1,6]. The prognosis of SCCUB is poor, especially in stage IV disease. According to current data, multimodal therapy is associated with better overall survival compared to monotherapy. Due to the rarity of this disease, robust comparative effectiveness studies are still needed.

P29 Impact of urodynamic findings in patients with amyotrophic lateral sclerosis and lower urinary tract dysfunction

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Introduction:

Amyotrophic lateral sclerosis (ALS) is a motor-neuron disease leading to progressive muscle atrophy, spasticity and weakness fatal life expectancy of 3–5 years* after diagnosis. Lower urinary tract dysfunction (LUTD) is reported by patients with ALS affecting quality of life**. The underlying causes are not finally understood and explanations for the reported urological disorders remain vague. Little is known about urodynamic findings and the impact of quality of life due to LUTD in this patient group. We report the outcome of urodynamic investigation in patients with ALS and bladder disorders.

Methods:

Between 2009 and 2020 184 patients with ALS were treated on an inpatient and outpatient basis in REHAB Basel. Patients who were examined urologically and underwent urodynamic investigation due to bladder disorders were eligible for this retrospective, single-center study. Data are shown in median with interquartile range.

Results:

76 ALS patients had an urological consultation and partly urotherapy. Only 11 patients (3 female, 8 male) underwent urodynamic evaluation, due to complex symptoms or insufficient therapy. Median age was 55 (53-72) years. Six patients (55%) were admitted because of appearance of urgency, pollakisuria was recognized in 6 patients (55%), urgency induced incontinence in 3 patients (27%) and 3 patients (27%) noticed need of press micturition to empty the bladder. Urodynamic investigation showed bladder hypersensitivity in 8 patients (73%), detrusor overactivity in 2 patients (18%) and non-relaxing-sphincter due to spastic pelvic floor in 8 patients (73%). Median bladder capacity was 400ml (355–487). Median maximum detrusor pressure was 39cmH₂O (28–48) showing a tendency to hypocontractility. Residual volume was 13ml (0–80). In 9 patients (82%) therapy was started or changed based on urodynamic investigation.

Conclusion:

We found a combination of disturbing storage symptoms primarily due to bladder hypersensitivity, and voiding symptoms, which seem mostly to be related to detrusor hypocontractility and non-relaxing pelvic floor. Because of the fatal diagnosis with short life expectancy the main focus should be on the quality of life. Bladder function should be evaluated actively and urodynamic diagnostic should be offered to specify urological dysfunction. In an ongoing trial we try to identify factors that affect quality of life by using a standard questionnaire (ICIQ-LUTS-QoL).

P30 Whole exome association study reveals potential risk-bearing germline variations for the development of muscle-invasive bladder cancer

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Introduction

Among the most important risk factors for the development of muscle-invasive bladder cancer (MIBC) are external exposures to carcinogens. Only scarce data exists on the impact of a genomic predisposition on the formation of MIBC. Previous reports identified an enrichment of germline variants (GV) in DNA damage repair (DDR) genes in MIBC patients. However, prior analyses relied on gene-panels enriched for DDR targets leading to a biased discovery. Here we performed a whole exome association study comparing the genome of patients with MIBC and to a control population.

Methods

In our study, we used the 412 non-cancerous samples from The Cancer Genome Atlas (TCGA) MIBC dataset. The samples from the 1000genomes (1000G) project functioned as a control group. Single-nucleotide polymorphisms (SNPs) were called and only germline SNPs with dbSNP information have been considered. We compared the prevalence of germline SNPs in MIBC and the 1000g cohort using Fishers exact test with Benjamini-Hochberg correction for multiple testing. A stepwise filtering was used for the identification of genes that are enriched in germline SNPs of MIBC. SNPs were further filtered with clinVar for clinical impact. Gene Set Enrichment Analysis was performed using the canonical pathways from MSigDB, extended by the APOBEC geneset.

Results

Overall, 375'886 SNPs were significantly different between TCGA and 1000G. A threshold of an odds-ratio > 10 and a false-discovery rate (FDR) < 0.05 was used to identify 2'538 most significant SNPs corresponding to 2'104 genes. Three of 43 enriched pathways were involved in immune-signaling. As a further filtering step, only SNPs occurring in clinVar and not being categorized as benign or likely benign were included. This resulted in 91 and 86 significantly different SNPs and genes, respectively. Among those, genes involved in e.g. the mismatch repair mechanisms (MSH6, MLH3) were present. However, this limited number of targets did not allow a robust pathway analysis.

Conclusions

Whole exome analysis of germline alterations in MIBC revealed SNPs and pathways that may be involved in the development of MIBC. Besides germline alterations involved in DNA homeostasis, immune- and T-cell receptor signaling were enriched in patients with MIBC. Although smoking exposure remains the most important risk factor, identification of germline variants may reveal a genomic predisposition for the development of MIBC and might suggest a genetic screening.

Posterdiskussion III – Unterer Harntrakt Discussion des posters III – Voies urinaires basses

P31 Single-stage buccal mucosal graft urethroplasty for meatal stenoses and fossa navicularis strictures: a monocentric

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OBJECTIVES:

To describe the operative technique and report outcomes from the largest series of patients who underwent single-stage dorsal inlay buccal mucosal graft urethroplasty (BMGU) for isolated meatal stenoses and fossa navicularis strictures.

PATIENTS AND METHODS:

First, we evaluated patients who underwent single-stage BMGU for distal urethral strictures (meatus and fossa navicularis) between 2009 and 2016 at our department. Clinical and surgical characteristics were prospectively collected in an institutional database. Recurrence was defined as symptomatic need of any instrumentation during follow-up, was retrospectively assessed by patient interview, and recurrence-free survival was plotted using Kaplan-Meier curves. Second, a systematic literature review was performed through Medline to summarize the available evidence on distal urethroplasty using flaps or grafts.

RESULTS:

Of 32 patients, 16 (50%) presented with a hypospadias-associated stricture, followed by seven (22%), five (16%), and four (13%) patients with iatrogenic, inflammatory, and congenital strictures, respectively. At a median follow-up of 42 months (IQR 23-65), single-stage dorsal inlay BMGU was successful in 22 patients (69%), and estimated recurrence-free survival rates were 79% and 74% at 12 and 24 months, respectively. Overall, 62 patients from five studies in the literature review underwent BMGU for isolated distal strictures and success rates ranged from 56 to 100%.

CONCLUSION:

Recurrent meatal stenoses and fossa navicularis strictures represent some of the most complex uro-reconstructive challenges. Inlay BMGU proves to be a valid and efficient last-resort single-stage technique. However, higher recurrence risk must be considered and staged urethroplasty should be discussed individually. Prospective randomized controlled trials are needed to prove the superiority of flaps, grafts or staged approaches over each other in this context.

P32 Buccal mucosal graft urethroplasty for radiation-induced urethral strictures: an evaluation using the extended Urethral Stricture Surgery Patient-Reported Outcome Measure (USS PROM).

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OBJECTIVES:

To evaluate objective treatment success and subjective patient-reported outcomes in patients with radiation-induced urethral strictures undergoing single-stage urethroplasty.

PATIENTS AND METHODS:

Monocentric study of patients who underwent single-stage ventral onlay buccal mucosal graft urethroplasty for a radiation-induced stricture between January 2009 and December 2016. Patients were characterized by descriptive analyses. Kaplan-Meier estimates were employed to plot recurrence-free survival. Recurrence was defined as any subsequent urethral instrumentation (dilation, urethrotomy, urethroplasty). Patient-reported functional outcomes were evaluated using the validated German extension of the Urethral Stricture Surgery Patient-Reported Outcome Measure (USS PROM).

RESULTS:

Overall, 47 patients were available for final analyses. Median age was 70 (IQR 65-74). Except for two, all patients had undergone pelvic radiation therapy for prostate cancer. Predominant modality was external beam radiation therapy in 70% of patients. Stricture recurrence rate was 33% at a median follow-up of 44 months (IQR 28-68). In 37 patients with available USS PROM data, mean six-item LUTS score was 7.2 (SD 4.3). Mean ICIQ sum score was 9.8 (SD 5.4). Overall, 53% of patients reported daily leaking and of all, 26% patients underwent subsequent artificial urinary sphincter implantation. Mean IIEF-EF score was 4.4 (SD 7.1), indicating severe erectile dysfunction. In 38 patients with data regarding the generic health status and treatment satisfaction, mean EQ-5D index score and EQ VAS score was 0.91 (SD 0.15) and 65 (SD 21), respectively. Overall, 71% of patients were satisfied with the outcome.

CONCLUSION:

The success rate and functional outcome after BMGU for radiation-induced strictures were reasonable. However, compared to existing long-term data on non-irradiated patients, the outcome is impaired and patients should be counseled accordingly.

P33 Long-term Outcome after Implantation of An Intraoperative Adjustable Non-Obstructive Bulbourethral Suspension for Post-Prostatectomy Incontinence

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Introduction

The bulbourethral composite suspension (BCS) with intraoperative urodynamic adjustment has routinely been used for more than 10 years in patients with moderate to severe stress incontinence in patients after radical prostatectomy.

Methods

We retrospectively reviewed outcomes in men who underwent this non-obstructive sling technique between 2009 and 2019 at our institution. The BUS, consisting of a non-absorbable polypropylene retropubic sling with a porcine dermis for urethral protection, was placed after suprapubic and perineal incision. Under urodynamic Valsalva leak point pressure measurement the sling was tied suprapubically. All patients received preoperative urodynamic evaluation. Patients with detrusor instability and urethral strictures were excluded. The primary outcome was changes in daily pad use. Secondary endpoint included peri- and postoperative complication rate.

Results

We performed BCS in 64 patients with a median age of 69.5 (range [R] 57 to 85) years. Median follow-up was five years (R 0.2 - 9.5). Daily median pad use decreased from preoperatively 4 (IQR= 3) to 1 postoperatively (IQR= 2.5), ($p < 0.01$). Of all patients 35 (56%) were totally continent (0-1 pad per day), 14 (22%) reported improved continence (reduced pad use), and 14 (22%) had no benefit. Because of persisting postoperative disturbing incontinence, 14 patients underwent during follow-up an artificial sphincter procedure. Complications occurred in ten cases (15%) and consisted of (n=8), which all healed spontaneously, and two bleeding situations, wherefrom one had to be threaten by coiling of a bleeding artery.

Conclusions

Bulbourethral composite suspension is a safe and efficient operative sling technique in patients with moderate to severe post-prostatectomy incontinence. This technique represents a good alternative to the artificial urinary sphincter implantation. A secondary artificial urinary sphincter implantation in patients with persistent incontinence following BCS is still possible.

P34 Comparison of the pelvic floor performed by perineal ultrasound in men before and after radical prostatectomy with or without incontinence

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Introduction

Post-prostatectomy urinary incontinence (PPUI) is a bothersome problem with a significant negative impact on quality of life. The aim of this study was to investigate static and dynamic pelvic floor measurements and to assess their predictive value in terms of PPUI.

Methods

We prospectively included patients who underwent robot-assisted radical prostatectomy (RARP) for intermediate to high-risk localized prostate cancer. All patients were preoperatively fully continent. The pelvic floor anatomy was examined by two-dimensional perineal sonography pre- and postoperatively at 6 weeks and 6 months after RARP. The measurements were taken during rest, Valsalva maneuver and actively elevating the pelvic floor by contraction. Following distances and angles were measured: Distance from the symphysis to the anterior bladder neck (SAB); diameter of the bladder-neck width (BNW); depth of bladder-neck (BND); angle of SAB in relation to the middle of the bladder neck measured from the symphysis (AA). Postoperatively, we assessed the daily pad use at 6 weeks and 6 months through a quality of life questionnaire. Patients were categorized as continent by the use of 0-1 pad/d and incontinent by ≥ 2 pad/d.

Results

Overall, 53 patients with a median age of 68 years (range 54 - 80) at the time of surgery were included. Six weeks postoperatively 23 men (43%) were continent and 34 (64%) after six month. Following mean results (measured in millimeter or degree) were found at rest pre- and postoperatively at 6 weeks and 6 months: SAB: 45/26/21mm, BNW: 16/18/17mm, BND: 6/10/8mm, AA: 11°/17°/19°.

There were no significant difference found for anatomic pelvic floor measurements preoperatively, six weeks and six months after prostatectomy comparing incontinent and continent patients.

Comparing content versus incontinent at six weeks, P-Values were 0.2 for SAB, 0.4 for BNW, 0.4 for BND and 0.4 for AA. P-Values after six month for SAB, BNW, BND and AA were 0.4, 0.1, 0.4 and 0.5, respectively.

The P-value comparing SAB mobility (SAB during Valsalva minus SAB during contraction) at six weeks was 0.5 and the one after 6 months 0.8.

Conclusions

In this study, we could not find a stable or dynamic sonographic measurement with predictive value of clinically significant PPUI. It seems that other clinicopathologic factors, such as the surgeon's abilities and never-sparing technique, are more important for PPUI.

P35 Multichannel cortical recordings of lower urinary tract sensory evoked potentials to advance the evaluation of viscerosensory pathways

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Background:

Assessment of lower urinary tract (LUT) afferents is highly demanded to better understand their involvement in various LUT symptoms. Cortical recording of sensory evoked potentials (SEPs) during LUT stimulation offers such assessment with information on nerve fiber integrity and conduction velocity. LUTSEP feasibility has been proven [1,2] and optimization of technique for bladder SEPs led to a 100% responder rate (RR), good reliability and high amplitudes using slower frequencies [3]. This is important for clinical implementation but requires evaluation for the urethra. Additionally, current bipolar recording has limited information on the cortical electrical field distribution to evaluate the cortical processing of LUT afferent signals. The aim was to expand findings to urethral stimulation sites and to systematically investigate the topographical distribution of LUTSEPs using cortical multichannel recording.

Methods:

- 90 healthy subjects (18-36 years) randomly assigned to one stimulation location: bladder dome, trigone, proximal, membranous (males only), or distal urethra.
- Repetitive electrical stimulation (0.5Hz,1.1Hz,1.6Hz) during 64 channel cortical recordings.
- Manual marker setting (P1,N1,P2 components) of Cz-Fz and Cz-AvgRef recordings.
- Scalp field data and microstates analysis using RAGU.

Results:

Stable urethral SEPs with the main components P1, N1, P2 and > 95% RR were recorded using slow frequency stimulation. While latencies did not show a frequency effect, amplitudes and RR decreased with higher stimulation frequencies.

N1 and P2 topographies presented central negativities and positivities at Cz. Analyses revealed consistent microstates, frequency effects for topographical distribution (N1,P2), and decreasing map strength with higher stimulation frequencies (P1,N1,P2). Cz-Fz recordings reported a higher RR compared to Cz-AvgRef.

Conclusions:

In complement to the bladder SEPs, optimized urethral SEPs now allow location-specific assessment of afferent nerve function for the entire LUT. Higher frequencies consistently led to lower amplitudes and RR, which is indicative of fiber refractoriness towards higher frequencies.

LUTSEP topographies indicate central generators in the somatosensory cortex, which are undetectable in a bipolar set-up. This novel, multichannel approach assesses LUTSEP amplitudes more comprehensively and might therefore be sensitive to pathological changes and its underlying cortical generators.

P36 Development of an appropriate sham procedure to investigate transcutaneous tibial nerve stimulation in randomized, sham-controlled, double-blind clinical trials

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Background:

Tibial nerve stimulation (TNS) is an effective and safe option to treat lower urinary tract symptoms (LUTS).[1,2,3,4] In contrast to the percutaneous approach, transcutaneous TNS (TTNS) is less expensive, completely non-invasive and therefore more attractive.[1] A few randomized controlled trials (RCTs) indicate limited evidence for TTNS effectiveness in LUTS therapy.[2] However, there is inconsistency in the sham and blinding setup which only partially allows to control for unspecific effects of TTNS.[1,2,4,5,6] Hence, for future RCTs, the question of a suitable sham protocol with conditions as similar as possible (procedure, electrode positions, size, threshold values and blinding) to the established TTNS arises.

Methods:

TTNS was performed with a commercial transcutaneous electrical nerve stimulation device (20Hz, 0.2ms). Three different sham electrode positions were tested:

- 1) at the lateral malleolus[7],
- 2) at the 5th metatarsal (below and on top of the little toe)[5],
- 3) at the heel of the foot sole assessing sensory and motor responses. For the most suitable positioning, two different electrode sizes (diameter: 2.5cm/3.2cm) were compared in 15 healthy subjects regarding feasibility, sensory/motor thresholds with type and localisation. Additionally, standardized procedures were developed in order to maintain blinding and control for unspecific TTNS effects (e.g. stimulation setup, interaction time).

Results:

With stimulation at the sole of the foot and lateral ankle, no or only very high motor thresholds could be determined. Compared to the other positions, the 5th metatarsal electrode positions proved to be most suitable for sham stimulation, with well tolerable and detectable sensory as well as motor responses in all subjects. Higher sensory thresholds, but lower motor thresholds were found for 3.2cm compared to 2.5cm electrodes ($p < 0.05$). Motor responses were observed at 3rd / 4th / 5th toe. Standardized subject instructions could be implemented.

Conclusions:

Among all tested electrode positions and electrodes, 3.2cm electrodes at 5th metatarsal positions proved to be most suitable as a sham-control condition for TTNS. Our optimized procedure comprising standardized stimulation setup and subject instructions is a promising approach to control for unspecific effects of TTNS. This is essential to investigate specific TTNS effects in multicenter RCTs to further our knowledge in the field of Neuro-Urology and neuromodulation.

P37 Stellenwert von Mirabegron in der Therapie der neurogenen Detrusorüberaktivität

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Einleitung

Die neurogene Blasenfunktionsstörung (NBFS) resultiert in erhöhten Drücken während der Speicherphase und Inkontinenz. Die Therapie mit Antimuskarinika (AM) muss häufig wegen Nebenwirkungen abgesetzt werden. Mit Mirabegron steht ein alternatives Medikament mit günstigerem Nebenwirkungsprofil zur Verfügung. Ziel der Studie war die Kontrolle der Effektivität im Verlauf über 6 Monate.

Material und Methoden

Einschluss aller Patienten mit chronischer (>1 Jahr) neurogener Blasenfunktionsstörung und urodynamisch nachgewiesener Überaktivität. Urodynamische Diagnostik vor Therapie und im Follow-up unter Therapie mit Mirabegron. Evaluation des Blasenmanagements, Inkontinenzepisoden und Analyse der urodynamischen Parameter.

Ergebnisse

Identifikation von 92 Patienten unter Therapie mit Mirabegron. Ausschluss von 29 Patienten wegen unvollständiger Daten. Die erste Kontrolle (n=63) erfolgte 3 Monate (1-53 Monate) nach Beginn der Therapie und die zweite 7.3 Monate (1-26 Monate) später (n=42). Reduktion des maximalen Detrusordrucks während der Speicherphase (p=0.01) von 35cmH₂O (Q25 23 / Q75 50cmH₂O) auf 26cmH₂O (Q25 15 / Q75 40cmH₂O), signifikante Vergrößerung der Blasenkapazität und Anstieg der Compliance von 30cmH₂O/ml (Q25 18 / Q75 47cmH₂O/ml) auf 63cmH₂O/ml (Q25 24 / Q75 109cmH₂O/ml), (p=0.001). Der Anteil an Patienten mit Harninkontinenz sank signifikant (p=0.002) von 62.3% auf 36.4% bei der Kontrolluntersuchung.

70% der Patientenerhielten eine additive Medikation mit AM. Nebenwirkungen bei 3 Patienten, Änderung der Therapie bei 5 Patienten.

Schlussfolgerungen

Mirabegron erzielt eine Verbesserung der urodynamischen Parameter, und ist eine wirksame und sinnvolle Medikation in der Therapie der neurogenen Detrusorüberaktivität.

P38 Sind 200 Einheiten Onabotulinumtoxin in der Behandlung der neurogenen Detrusorüberaktivität bei Personen mit chronischer Rückenmarksverletzung ausreichend?

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Hintergrund:

Die neurogene Detrusorüberaktivität (NDO) ist durch eine reduzierte Blasenkapazität und einen erhöhten Detrusordruck während der Speicherphase gekennzeichnet. Antimuskarinika oder Botulinumtoxin-Injektionen in den Detrusor sind Therapieoptionen für NDO. Bei Patienten mit idiopathischer Detrusorüberaktivität erfolgt die Injektion mit 200 Einheiten (initial 300), um das Risiko der Restharnbildung zu minimieren. Bei diesen Patienten zeigten sich vergleichbare Ergebnisse mit 200 vs. 300 Einheiten. Bei Patienten mit NDO bestand das Risiko, dass die reduzierte Dosis von 200 Einheiten, den zusätzlichen Bedarf an Antimuskarinika erhöhen könnte. Wir haben daher den Effekt von 200-Einheiten (Onabotulinumtoxin) Injektionen bei der Behandlung der NDO bei Personen mit chronischer Rückenmarksverletzung (SCI) untersucht.

Methoden

Mit Hilfe unserer Datenbank wurden Patienten mit chronischer (> 12 Monate) NDO aufgrund von SCI identifiziert, die mit Onabotulinumtoxin-Injektionen behandelt wurden. Patienteneigenschaften, Daten zum Blasenmanagement, Inkontinenzepisoden und Blasenmedikation sowie urodynamische Parameter wurden erfasst. Die Unterschiede zwischen den Effekten von 200- und 300-Einheiten-Onabotulinumtoxin-Injektionen wurden unter Verwendung des Wilcoxon-Signed-Rank Tests und des McNemar-Tests untersucht. Die Daten werden als Median- und 95% -Konfidenzintervalle dargestellt.

Ergebnisse

Die Daten von 56 Patienten mit einem Durchschnittsalter von 49 (21-63) Jahren und einer mittleren NDO-Dauer von 12 (2-43) Jahren wurden analysiert. Zusätzliche Medikamente zur NDO-Therapie (Antimuskarinika, Mirabegron) wurden nach der Behandlung mit 200 bzw. 300 Einheiten Onabotulinumtoxin von 37,5% resp. 21,4% ($p = 0,064$) eingenommen. Es gab keinen signifikanten Unterschied beim maximalen Detrusordruck während der Speicherphase (20 cm H₂O, 12/24 cm H₂O gegenüber 17 cm H₂O, 11/21 cm H₂O) ($p = 0,31$), der Blasenkapazität (460 ml, 440/480 ml gegenüber 455 ml, 420/460 ml) ($p = 0,22$) und der Detrusor-Compliance (42 cmH₂O/ml, 34/47 cm H₂O/ml gegenüber 36 cm H₂O/ml, 30/55 cm H₂O/ml) ($p = 0,46$) zwischen der Therapie mit 200- und 300-Einheiten-Onabotulinumtoxin. Darüber hinaus gab es keinen signifikanten ($p = 0,39$) Unterschied in der Kontinenzrate zwischen den beiden Gruppen (62,5% gegenüber 73,2%).

Schlussfolgerungen

Die Behandlung von NDO aufgrund von SCI mit 200 Einheiten Onabotulinumtoxin scheint genauso wirksam zu sein wie die Behandlung mit 300 Einheiten.

P39 Multiple sclerosis patients with mild LUTS: findings at first urodynamic evaluation

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Aims of study:

Neurogenic lower urinary tract dysfunction (NLUTD) is very frequent in the presence of multiple sclerosis (MS). Despite the high prevalence of lower urinary tract symptoms (LUTS), risk of renal function deterioration remains low when compared to other neurologic pathologies, such as myelomeningocele and spinal cord injury. Thus, the need for urodynamic evaluation in these patients remains unclear. The aim of our study was to assess the presence and significance of pathological urodynamic findings in multiple sclerosis patients with mild LUTS.

Material and methods:

Retrospective analysis of 75 MS patients referred for primary neurourological work-up was performed. Clinical parameters taken into account were age, sex, type and duration of MS, and Expanded Disability Status Scale (EDSS). A health questionnaire was initially offered to all patients. Presence of dysuria, pollakiuria, urgency and incontinence were evaluated. Patients were split into two groups. Mildly symptomatic if they had scores of 0 or 1; moderately symptomatic if they presented ≥ 2 of these symptoms. All patients underwent a standard video-urodynamic examination. Correlation between clinical picture and urodynamic findings such as post void residual volume >150 ml (PVR), detrusor overactivity (DO) and detrusor sphincter dyssynergia (DSD) was assessed.

Results:

26/75 patients (34.7%) presented with mild (group A) and 49/75 (49%) with moderate (group B) symptoms. Basic parameters were similar in both groups except the EDSS score which was higher in group B than group A (3.5 (2.5 - 4.5) vs 2 (1.5 - 3.5)), $p < 0,001$. Group A patients mainly complained of dysuria (34.6%) while in group B urgency was the most prevalent symptom (86% of the patients). Detrusor overactivity was significantly more frequent in group B than group A patients (55% vs 23%). Multivariate analysis revealed urgency as a significant predictive factor for detrusor overactivity (OR: 4.5, 95% CI: 1.64 – 15.73, $p = 0.01$). Dysuria was significantly associated with DSD (OR: 5.59, 95% CI = 1.81-17.29, $p = 0.03$) and pathological PVR (OR : 7, 95% CI = 2.30-21.27, $p = 0.001$). In univariate analysis, higher EDSS was associated with DO and pathological PVR, while in multivariate analysis, it was not.

Conclusions:

The presence of dysuria or urgency in MS patients seems to be an independent predictive factor of lower urinary tract dysfunction. In their presence, urodynamic evaluation should be considered.

P40 Onabotulinum toxin type-A detrusor injections for the treatment of neurogenic detrusor overactivity in patients with multiple sclerosis

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Context and objective

Lower urinary tract dysfunction (LUTD) is very common in multiple sclerosis (MS). When the usual pharmacological treatment fails, onabotulinum toxin type-A (Onabot/A) detrusor injections can be proposed. However, the long-term evolution of lower urinary tract dysfunction and predictive factors for resistance to pharmacological treatment with consecutive need for Onabot/A detrusor injections in patients with MS are unknown. Primary outcome was to assess long-term changes in voiding function and to determine predictive factors for resistance to pharmacological treatment, secondary outcome was the efficacy of Onabot/A detrusor injections in patients with MS.

Methods

Retrospective analysis of 111 patients with MS who had undergone at least one follow-up urodynamic investigation (UDI) additional to the initial UDI. We analyzed and recorded baseline and follow-up lower urinary tract symptoms (LUTS), complications, Expanded Disability Status Scale (EDSS), and urodynamic findings. A multivariate regression model was used to evaluate any association of clinical parameters (age, sex, duration of MS, EDSS, and number of LUTS (urgency, frequency, urinary incontinence, and dysuria)), and urodynamic parameters and the occurrence of resistance to pharmacological treatment. Efficacy of Onabot/A detrusor injections was assessed using T test and Chi-square test to determine statistical significance (p value < 0.05).

Results

71 women and 40 men with MS were followed for a mean of 3.5 +/- 2.0 years. Resistance to pharmacological treatment and need for Onabot/A detrusor injections was observed in 22% (24/111) of patients. Multivariate modeling revealed higher patient age (OR:1.05, 95% CI:1.00-1.10, $p = 0.05$) and larger number of lower urinary tract symptoms (OR:2.41, 95% CI:1.14-5.06, $p = 0.02$) as clinical parameters significantly associated with resistance to pharmacological treatment and consecutive need for Onabot/A detrusor injections. Significant urodynamic changes after treatment were observed.

Conclusion

Higher age and higher number of LUTS are significantly associated with resistance to pharmacological treatment. Screening of patients presenting higher age and higher number of LUTS may allow early-detection of patients who will fail pharmacological treatment and therefore accelerate the escalation in the therapeutic ladder. Onabot/A detrusor injections improve LUTS control and detrusor overactivity in MS patients.

P41 Is Expanded Disability Status Scale (EDSS) enough to predict risk factors for upper urinary tract (UUT) damage in patients with multiple sclerosis?

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Context and objective

Neurological lower urinary tract dysfunction (NLUTD) is very common in patients with multiple sclerosis (MS). NLUTD not only has a major impact on quality of life, but might even lead to UUT damage. While there are well-known urodynamic risk factors for UUT damage, well established clinical prediction parameters are lacking. An Expanded Disability Status Scale (EDSS) ≥ 5.0 has been previously reported to be a good predictor of urodynamic risk factors for UUT damage. The aim of our study is to evaluate whether EDSS and/or other clinical parameters are able to predict urodynamic risk factors for UUT damage in our MS population.

Method

We retrospectively reviewed 201 patients with MS referred for primary neuro-urological work-up including urodynamic investigation (UDI), from August 2009 to February 2020. A multivariate logistic regression model was used to evaluate any association of clinical parameters (age, sex, duration of MS, EDSS, and number of LUTS (urgency, frequency, urinary incontinence, and dysuria)) and the occurrence of urodynamic risk factors (bladder compliance < 20 mL/cmH₂O, maximum detrusor pressure > 40 cmH₂O, vesico-uretero-renal reflux and detrusor overactivity combined with detrusor sphincter dyssynergia).

Results

Multivariate modeling revealed EDSS, male gender, and absolute number of LUTS as clinical parameters significantly associated with urodynamic risk factors for UUT damage ($p = 0.05$, $p = 0.01$, $p = 0.02$, respectively). Exclusive use of an EDSS cutoff of 5.0 in order to detect urodynamic risk factors in our MS population, showed low sensibility and specificity. A nomogram combining EDSS ≥ 5 , male gender and number of LUTS allowed to better estimate individual risk of urodynamic risk factors for UUT damage.

Conclusion

A nomogram including EDSS ≥ 5 , male gender and number of LUTS seems to allow risk prediction of urodynamic risk factors for UUT damage in MS patients. These findings need validation by larger, multicentric studies.

P42 Outcome of dorsal onlay graft urethroplasty for long non-traumatic bulbo-membranous urethral strictures

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Introduction:

Non-traumatic bulbar urethral strictures involving the membranous portion are usually treated by transperineal anastomotic urethroplasty. The preference for this technique is likely influenced by the familiarity and experience with trauma-related injuries. However, this procedure may have limitations, especially for long strictures of more than 2 cm of length, and risks in terms of incontinence and impaired bulbar vascularization. In some cases, substitution urethroplasty should be therefore favoured but the proximal fixation of the graft may be challenging in such a deep location into the perineum, requiring judicious technical tricks. We assessed the feasibility and outcomes of dorsal onlay graft (DOG) urethroplasty for long non-traumatic bulbo-membranous urethral strictures using a modified Barbagli technique.

Materials and methods:

Single-centre retrospective study of 14 patients with non-traumatic bulbo-membranous urethral strictures who underwent DOG urethroplasty using either penile skin (PS) or buccal mucosa (BM) graft between 2013 and 2019. A modified Barbagli technique was performed using a nasal speculum to expose the proximal lumen and stitch the graft with J-shaped needles. Clinical outcome was considered a failure if a subsequent operative procedure was needed, including dilation. Ranges are expressed by interquartiles unless precised.

Results:

12 out of 14 patients had complete data. PS was used in 5 (42 %) of them and BM in 7 (58 %) with graft choice made according to patient preference and/or past history of circumcision. Median age was 58 years and median stricture length was 4 (2.5-10) cm. At a median follow-up of 18 (1-60) months, we achieved a success rate of 100 %. Etiology of stenosis was mainly post-catheter trauma (5 patients (42 %)). Median post-operative Qmax increased 4.2 folds. There was one Clavien-Dindo IIIb (severe uretrorrhagia with bladder clot requiring endoscopic hemostasis). No patient reported urinary incontinence and 2 of them (17 %) complained of de novo erectile dysfunction.

Conclusion:

Substitution urethroplasty to treat proximal bulbar strictures has been sparsely used compared to anastomotic urethroplasty, but it appears to be a useful technique in patients with long strictures (> 2 cm), with a high success rate at short term follow-up, which might be mitigated by further pending follow up. There was no incontinence and little impact on erectile dysfunction.

P43 Protocol for a multicenter, randomized, sham-controlled, double-blind clinical trial investigating transcutaneous tibial nerve stimulation for treating neurogenic lower urinary tract dysfunction (bTUNED)

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Introduction:

Many patients with neurological diseases suffer from neurogenic lower urinary tract dysfunction (NLUTD), which often severely impairs quality of life, due to urinary urgency with or without incontinence and voiding dysfunction. High intravesical pressures may jeopardise the upper urinary tract caused by detrusor overactivity with concurrent detrusor sphincter dyssynergia and/or low bladder compliance. The treatment of NLUTD is a challenge since conventional conservative therapies often fail and more invasive treatments such as onabotulinumtoxinA injections, bladder augmentation, and urinary diversion must be considered. Neuromodulation therapies may be alternative non-invasive treatment options. Tibial nerve stimulation (TNS) is an effective and safe treatment for idiopathic overactive bladder proven in randomized controlled trials (RCTs), but its transcutaneous application (TTNS) and value in neurological patients is still unclear.

Methods:

bTUNED is a multicenter, randomized, sham-controlled, double-blind clinical trial performed in 7 centers worldwide (Basel, Bellinzona, Antwerp, Florence, Rome, São Paulo, Zürich). 240 patients (refractory NLUTD) will be included, randomized 1:1 into verum or sham TTNS and stratified by study center and cause of NLUTD. The intervention is performed twice a week for 30 minutes during a period of 6 weeks. The primary outcome is the success of TTNS defined as reduction in incontinence rates, reduction in micturition/catheterization frequency and reduction of post void residual. Secondary outcomes are changes in clinical symptom scores, bladder diaries, urodynamic and neurophysiological parameters. Safety of TTNS as the tertiary outcome.

Results:

Over the course of 2 years the preparatory phase of bTUNED has been successfully completed. To harmonize all study procedures among study centres, standardized procedures and checklists have been developed and implemented. Pilot verum and sham TTNS to evaluate and improve patients' comfort and blinding techniques revealed positive results. The RCT has been approved by the respective ethics committees and recruitment has started.

Conclusions:

bTUNED is the first adequately powered, randomized, sham-controlled, double-blind trial assessing TTNS for treating NLUTD. It will provide significant insights into efficacy and safety of TTNS in patients suffering from NLUTD and has the potential to completely revolutionize the management of NLUTD in daily clinical practice.

P44 Detrusor sphincter dyssynergia in 2020: Time to refine the ICS definition?

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Introduction:

According to the International Continence Society (ICS) terminology of 2002, detrusor sphincter dyssynergia (DSD) is defined as a detrusor contraction concurrent with an involuntary contraction of the urethral and/or periurethral striated muscle. Although DSD typically occurs in patients with a supra-sacral lesion, it is also found in non-neurological patients and even in healthy volunteers. Thus, we investigated if more specific DSD definitions might distinguish between various pathologies and thereby influence the management in daily clinical practice.

Methods:

Based on our prospective database, we identified 153 patients (81 patients with classic supra-sacral spinal cord injury and 72 patients with no underlying neurological disorder) who underwent video-urodynamics and who were diagnosed with DSD according to the ICS definition. We determined for all of these patients the DSD type according to the classifications by Blaivas (type 1-3), Weld (type 1 and 2) and Yalla (type 1-3). Differences in patients and DSD types were assessed.

Results:

Comparing patients with spinal cord injury to those with no underlying neurological disease, no statistically significant differences ($p > 0.05$) were found in the distribution according to DSD classifications by Blaivas (type 1: 22 versus 18%, type 2: 44 versus 39%, type 3: 34 versus 43%), Weld (type 1: 48 versus 38%, type 2: 52 versus 62%) and Yalla (type 1: 1 versus 8%, type 2: 63 versus 51%, type 3: 36 versus 41%).

Conclusions:

The current DSD definition by the ICS has stood the test of time. The more complex classifications by Blaivas, Weld or Yalla cannot seriously compete with the ICS binary yes-no definition which is pragmatic and straightforward for managing patients in daily clinical practice.

P45 Comparison of the artificial urinary sphincter and the adjustable sling in the treatment of postprostatectomy male urinary incontinence

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Introduction

Sphincter urinary incontinence (SUI) in men can be a complication of prostatic surgery. It's reported incidence after radical prostatectomy varies widely from 1 to 57%. This variation can be explained by different definitions of continence and methods of assessment.

When the conservative treatment fails (fluid restriction, pelvic floor exercises, biofeedback) it requires surgical treatment that includes an artificial urinary sphincter (AUS, considered the gold standard treatment), periurethral bulking agents, and more recently, the adjustable sling techniques (AS).

Our purpose is to compare the outcome of the AUS and the AS techniques with patients presenting moderate to severe SUI after radical prostatectomy.

Methods

We included in our study patients with moderate to severe incontinence that were treated surgically by the AS (68 patients) or the AUS (90 patients). The preoperative evaluations included history, physical examination and pad tests. The follow-up examinations were performed at 1, 6, and 12 months postoperatively and annually thereafter. We used the Patient Global Impression of Improvement (PGI-I) for satisfaction measurement.

Results

The average age for the AS group was 72 years old (58-88) vs 69 yo (42-80) for the AUS group.

We selected patients with moderate to severe SUI with pad tests of 150 g or more, or using 3 or more protective pads per day.

The outcomes (AS vs AUS) regarding the post-surgical "dryness" (considered by the use of less than 2 pads per day) were 76% vs 88% ($p < 0.05$).

The activation of the AS was made the day after the surgery, where the SUA activation was made, in average, 6 weeks after the surgery.

Re-operation for adjustment (AS vs SUA) was seen in 83% ($n = 11$) vs 6% ($n = 5$) - $p > 0.05$.

The need to remove the entire system due to complications was seen in 2 (3%) in the AS group vs 5 (3%) of the SUA patients ($p < 0.05$).

The PGI-I was 1 up to 3 in 63% ($n = 42$) of the AS patients vs 81% ($n = 73$) of the SUA patients ($p > 0.05$).

Conclusion

The outcome regarding efficacy isn't significantly better with the SUA, and the complications with each technique were estimated at 3%. The satisfactions seems to be better achieved with the SUA.

The SUA is the gold standard for the moderate to severe SUI treatment but the AS seems to be a less invasive alternative, with less prosthetic material implanted.

P46 Evaluation of Urinary Sphincter Function by MR Diffusion Tensor Imaging

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Purpose:

The aim of our study was to confirm the feasibility of diffusion tensor imaging (DTI) for evaluation of the female urinary sphincter function based on differentiation between rest and muscle contraction.

Methods:

MRI of the lower pelvis was performed at 3T in 10 healthy female volunteers (21-36 y., BMI 20.8±3.6 kg/m²) between June and July 2019. High-resolution T1 and T2 images were acquired for anatomical reference, and following DTI performed in four experiment phases: twice during rest (denoted 'Rest-1', 'Rest-2') and contraction ('Contraction-1', 'Contraction-2'). Manual segmentation of the urinary sphincter and the levator ani muscles was performed by two independent readers. Mean diffusivity (MD) and fractional anisotropy (FA) values derived from DTI volumes were compared in search for significant differences between the experiment phases. Inter-reader agreement was assessed by intraclass correlation coefficient (ICC).

Results:

Kruskal-Wallis test showed significant differences between MD values among all the experiment phases, by both independent readers (1st: $\chi^2(3,76)=17.16$, $p < 0.001$ and 2nd: $\chi^2(3,76)=15.88$, $p < 0.01$). Post-hoc analysis revealed differences in MD values by both readers between: Rest-1 vs. Contraction-1 (least $p < 0.05$), Rest-1 vs. Contraction-2 ($p < 0.01$), Rest-2 vs. Contraction-1 ($p < 0.03$), Rest-2 vs. Contraction-2 ($p = 0.02$) with overall mean 'Rest' to 'Contraction' $\Delta MD = 20.6\%$. No MD difference was found between Rest-1 vs. Rest-2 and Contraction-1 vs. Contraction-2, and between FA values among all the experiment phases. Inter-reader agreement was found as ICC = 0.85 (MD) and ICC = 0.79 (FA).

Conclusions:

DTI might become a supporting imaging tool to evaluate pelvic floor muscle function, including incontinence.

P47 Multisystem Cell Therapy for the Improvement of Urinary Continence

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Background:

Stress Urinary Incontinence (SUI) is affecting over 400m people worldwide. Existing conventional and surgical procedures only provide limited success. Based on the promising results from various pre-clinical studies, we developed a protocol to isolate, expand and harvest muscle precursor cells (MPC) from a muscle biopsy of the lower limb to restore muscle function. We aim to produce autologous MPCs for the injection into the external urinary sphincter and to combine it with electro-magnetic stimulation. Cell therapies classify generally as advanced therapy medical products (ATMP) and represent various new possibilities in tissue regeneration. ATMP production is strictly regulated via Good Manufacturing Practice (GMP) guidelines. These guidelines help allow the safe translation of basic research data into ATMPs but their implementation is quite time- and resource-consuming. Here, we aim to provide an overview of related preparatory work until the first patient in a phase I clinical trial to treat SUI.

Methods:

The precise isolation, expansion, identification and transplantation the MPCs is complex. The successful validation of the manufacturing process according to GMP includes: verification of all used analytical methods, stability and transport studies to determine the shelf life of the final product, validation of the whole manufacturing process including the aseptic production and performing personnel as well as injection simulations on corpses. Results: All analytical methods were verified to provide reliable values during production. Stability studies confirmed that cell viability of 80% may be kept for 24 hours after preparation of the final product. Seven study and 2 process verification runs were performed and injection simulations showed that precise application into the sphincter muscle is possible through ultrasonographical guidance.

Conclusion:

ATMPs have immense potential to treat a huge variety of illnesses, but their potential for contamination and misproduction must be curtailed via stringent supervision. Setting up a GMP-compliant system is extremely costly and time consuming, but, given the potency of tomorrow's treatment, becoming more and more necessary. In our phase I clinical trial, we are working towards providing a novel autologous MPC-based therapy to treat SUI patients with a regenerative approach. The validation was finished end of 2019 and the first patient successfully treated in March 2020. The study is ongoing.

P48 Short-term urologic complications and changes after intrathecal baclofen pump implantation

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Background

Spasticity is a burden commonly seen in patients with central neurological disorders. While there is a variety of oral spasmolytic drugs as a first therapeutic many patients require a more invasive approach. Although Botulinumtoxin injection is the most widely used treatment for focal spasticity, implantation of a pump for the intrathecal baclofen (ITB) remains the treatment standard for severe spasticity. [1] While few urologic reports of the late 1980s and animal models suggest a suppressing effect of ITB on detrusor activity and urethral sphincter spasticity, current studies focusing on the clinical relevance are missing.[2-4]

Methods

We searched our clinical reporting system in all 128 patients with an ITB pump implanted from 1991 until 2019 that were treated in the REHAB Basel. Our documentation system was searched for clinical relevant changes involving bladder function until 4 months after pump implantation.

Results

In 52 cases the documentation was not sufficient for analysis and therefore these patients were excluded. Of the remaining 76 patients we identified 7 with urologically relevant events. 4 of them had supraspinal injury (bleeding, trauma), 2 patients presented with paraplegia due to spinal cord injury (sub D4 and sub D7) and 1 patient with Multiple sclerosis. In 2 patients increasing post void residual volume (RV) after ITB pump implantation was reported, this effect vanished with ITB dose reduction. In 5 patients we identified an effect on external urethral sphincter function. 3 of 5 reported a de-novo urinary incontinence (UI). In one of these incontinence was dose dependent, occurring only above dosages of 160 µg/d. In 2 of 5 patients urodynamic findings prior to ITB pump implantation showed neurogenic detrusor overactivity (DO) with only minimal UI. After implantation urodynamic studies showed a reduction of sphincter spasticity leading to DO induced UI without any RV.

Conclusion:

In accordance to available literature we found a clinical relevant effect of ITB pump implantation on detrusor or urethral sphincter function in 9% of patients. Severe and refractory limb spasticity is the most prevalent indication for ITB pump implantation. Therefore, effects on bladder function may be underreported in these patients. Based on our experience, in our clinic these patients will be consistently examined clinically and urodynamically, to be able to predict urological complications after implantation and prevent them if necessary.

Posterdiskussion IV – Niere

Discussion des posters IV– Rein

P49 Systematic assessment of information about surgical urinary stone treatment on YouTube

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Purpose

To systematically assess the quality of videos on the surgical treatment of urinary stones available on YouTube using validated instruments.

Methods

A systematic search for videos on YouTube addressing treatment options of urinary stones was performed in October 2019. Assessed parameters included basic data (e.g. number of views), grade of misinformation reporting of conflicts of interest. Quality of content was analyzed using the validated DISCERN questionnaire. Data were analyzed using descriptive statistics.

Results

A total of 100 videos with a median of 26'234 views (1'020 – 1'720'521) were included to the analysis. Of these, only 26 videos were rated to contain no misinformation and only nine disclosed potential conflicts of interest. Overall, the median quality of the videos was low (2 out of 5 points for DISCERN question 16). Videos uploaded by healthcare professionals and medical societies / organizations offered significantly higher levels of quality. In particular, the videos provided by the EAU achieved the highest rating with a median score of 3.0.

Conclusions

The majority of videos concerning the surgical treatment of urinary stones have a low quality of content, are potentially subject to commercial bias and do not report on conflicts of interest. Videos provided by medical societies, such as the EAU, provide a higher level of quality. This highlights the importance of active recommendation of evidence-based patient education materials.

P50 The German linguistic validation of the Wisconsin Stone Quality Of Life Questionnaire (WisQoL)

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Purpose

The Wisconsin Stone Quality of Life questionnaire (WisQoL) is a disease specific, health related quality of life measure designed for patients who form kidney stones. The goal of this study was to develop and validate a German version of WisQoL.

Methods

The German version of the WisQoL was developed following a standardized multistep process. Patients were recruited prior to stone treatment, and completed the questionnaire as well as the SF-36v2 (36-Item Short Form Health Survey). This was repeated 1, 3 and 6 months after stone surgery. Scores of the 28 questionnaire items were summarized into sum scores for four domains and a total score. The psychometric properties of the questionnaire were statistically analyzed.

Results

The German WisQoL demonstrated excellent internal consistency (Cronbach's $\alpha > 0.90$ for all domains at all visits). All inter-domain associations were positive. The test-retest reliability for patients with unchanged self-reported health state was considered satisfactory (Spearman's rho for total score 0.70 [95% CI 0.55 to 0.80]). The German WisQoL demonstrated good convergent validity with the validated SF-36v2 (correlation between corresponding items 0.44 to 0.64). All domain scores showed significant sensitivity to change induced by stone treatment ($p \leq 0.05$). Total WisQoL scores generally improved during the first three months following stone treatment and remained stable thereafter.

Conclusion

The German WisQoL proved to be a reliable and robust instrument to evaluate health related quality of life measures of kidney stone patients in the clinical setting. It is expected to be of use for further research in patients with kidney stones.

P51 Oral chemolysis is an effective, non-invasive therapy for urinary stones suspected of uric acid content

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Objectives:

To evaluate the effectiveness of oral chemolysis (alkalization of urine) in the management of suspected uric acid stones and to identify factors affecting its outcome.

Methods: Retrospective single-center cohort study of 216 patients with 272 renal and/or ureteral stones treated with oral chemolysis from 01/2010 to 12/2019. Patients with low urine pH (< 6), low stone density upon non-contrast enhanced computed tomography (NCCT), radiolucent urinary stones on plain radiography, and/or a history of uric acid urolithiasis were included. Patients with ureteral stones < 6mm were excluded since stones this small are very likely to pass spontaneously. Potassium citrate and/or sodium/magnesium bicarbonate were used for alkalization (target urine pH: 6.5 – 7.2). The stone-free status of each patient was evaluated after 3 months using NCCT. Multivariate logistic regression analysis was used to assess factors affecting outcome.

Results: Median patient age was 63 years. Median stone size was 9 mm, median stone density 430 Hounsfield Units. 51.8% of stones were located in the ureter. Chemolysis was complete in 61% of stones at 3 months, partial in 14%; 25% of stones could not be dissolved. Lower stone density (OR = 0.997 [CI: 0.994 - 0.999]; p = 0.008) and smaller stone size (OR = 0.959 [CI: 0.924 - 0.995]; p = 0.025) significantly increased the success rate of oral chemolysis.

Conclusions:

Oral chemolysis is an effective, non-invasive therapy for urinary stones suspected of uric acid content, with a complete response rate of 61% at 3-month follow-up. Lower density and smaller size significantly improved its success rate. More precise stone diagnostics to exclude non-uric-acid stones could further improve outcome.

P52 Outcome Groups and a Practical Tool to Predict Success of Shock Wave Lithotripsy in Daily Clinical Routine

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Purpose:

To improve outcome prediction of extracorporeal shock wave lithotripsy (SWL) by development of a model based on easily available clinical and radiographical predictors and suitable for daily clinical use

Materials and Methods:

We evaluated predictive factors for SWL success in 517 consecutive patients suffering from urinary calculi who underwent SWL between 2010 and 2018. Analyses included descriptive statistics, receiver operating characteristic statistics and logistic regression. Predictive value was improved by combining parameters using model selection and recursive partitioning.

Results:

Of the 517 patients, 310 (60.0%) had a successful SWL. Best individual predictor of SWL success was mean attenuation (MAV), with an area under the curve (AUC) of 0.668, and an optimal cutpoint (OC) of 987.5 HU. The best multivariable model, including MAV, stone size, skin to stone distance (SSD), presence of an indwelling stent, and four interaction effects, yielded an AUC of 0.736. Recursive partitioning would categorize patients into three outcome groups with high (76.9%), intermediate (41%) and low (10%) success probability. High probability of SWL success (76.9 %) was found for patients with a stone with MAV \leq 987 HU or with MAV $>$ 987 HU but stone size \leq 11 mm and SSD (45°) \leq 88 mm.

Conclusions:

A model based on four established predictors, and provided as an Excel[®]-Tool, can clearly improve prediction of SWL success. In addition, patients can be classified into three defined outcome groups based on simple cutpoint combinations. Both tools improve informed decision-making in daily clinical practice and might reduce failure rates.

P53 How we implemented PCNL at CHUV: preliminary results of our PCNL cohort

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Background and objectives

The prevalence of nephrolithiasis is increasing over the past decades. Percutaneous nephrolithotomy (PCNL) is the intervention of choice for kidney stones > 2 cm according to current guidelines which makes it an essential procedure of the endoscopic armamentarium. As it was not commonly performed in the canton of Vaud in the past few years, we newly implemented the percutaneous technique at our University Center. We present the preliminary results of our cohort and the evaluation of the number of cases.

Material and methods

Retrospective analysis of a consecutive series of percutaneous interventions (Mini-PCNL; PCNL) performed at our institution since the introduction of the procedure in September 2018

Results

Thirty-five procedures (27 PCNL, 8 Mini-PCNL) were performed since September 2018, and another 10 are currently (April 2020) scheduled. There was an increase in the number of interventions over time with 1 – 2 patients operated each of the first three trimesters, and 15 patients in the last trimester. Before 11/2019 (change of the Head of Department), 38% of patients were addressed by external urologists, while it was 59% of patients subsequently. Median stone size was 28 mm (IQR: 22 – 40). Stone analysis revealed calcium oxalate monohydrate in 31%, dihydrate in 6%, struvite in 22%, and others in 41%. Median operative time was 130 minutes (IQR: 105 – 167). 66% of patients were stone free after one percutaneous intervention and did not need further treatment: 50% (4/8) after Mini-PCNL; 70% (19/27) after PNL. Postoperative stone free rates were significantly associated with complexity of the intervention as measured by Guy's stone score (1-4): 100% (3/3) with score 1; 67% (6/9) with score 2; 63% (10/16) with score 3, and 50% (3/6) with score 4; ($p = 0.138$). Overall complication rate was 37% (13/35). Nine patients (26%) presented post-operative complications Clavien-Dindo grade ≥ 2 : Infections (4/9), post-operative bleeding (2/9), respiratory and cardio-vascular (2/9) and ureteral stricture (1/9).

Conclusion

With the implementation of (Mini-) PCNL procedures at CHUV with a high quality standard an increasing number of patients are referred. The number and severity of complications are in the low range as compared to those reported in the literature. Stone free rates are inversely associated with higher complexity.

P54 Ureteroscopies in kidney transplant and urinary diversions: feasibility and long term outcome of stricture management

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Context

Ureterorenoscopies (URS) in kidney transplants (KT) and urinary diversions (UD) are technically challenging and thought to be at higher risk of infection. Our goal was to assess the feasibility of URS in this challenging setting. We also compared the success rate of endoscopic ureteral stricture treatment (UST) between KT, UD, and native ureters (NU).

Method

Single institution retrospective review of all URS performed between 01.2013 and 04.2020 including patients who underwent URS in KT, UD, or who had UST. Classic antibiotic use (CA) was defined as a single intraoperative dose for negative culture or 2-days oral/1-day intravenous preoperative treatment for infected culture without postoperative antibiotics. Success was defined as the absence of obstacle on postoperative imaging for UST. Complications were rated according to the Clavien score.

Results

43 patients were eligible: 13 UD, 13 KT & 17 UST for a total of 55 procedures. In KT & UD, retrograde access was feasible in 93 and 69 %. Antegrade access was necessary in 10 cases, 1 (6%) of KT and 9 (45%) of UD intervention, with a feasibility of 100% and 89%. CA was used in 73% and 60% of KT and DU – only 1 UD patient (5%) developed postoperative urosepsis.

30 patients underwent UST: 17 NU, 9 UD, 4 KT, for a total of 37 procedures. 33/37 (89%) were feasible while all 4 failures occurred in UD. 9 URS were antegrade (24%), 7 in UD, 1 in NU, and KT. 1 patient was lost to follow-up, 3 were recently operated. Of 26 followed-up patients, 12 (46%) did not develop recurrence within a follow-up of 31.4 months. Three recurrences (12%) occurred after stent removal within an interval of 1.1 months. Stents were not removed in 11 patients (44%). Long term success was 50%, 33% and 50% in NU, UD and KT ($p = 0.77$). Twenty-four patients had 1 incision, 5 had 2 and 1 had 3 incisions, with respective success rate of 55%, 20% and 0% ($p = 0.24$). Success rate was 62% in incision-dilatation and 40% in dilatation alone ($p = 0.55$). CA was used in 70% of UST, 2 patients (5%) developed postoperative urosepsis. No grade ≥ 3 complications occurred.

Conclusion

URS in KT and UD are feasible, have low morbidity, and can often be treated under conventional antibiotic prophylaxis. UD strictures are technically difficult to manage and frequently require antegrade access, underlining the need for a specialized endoscopic team. Incision-dilatation was more efficient than dilatation alone, however without statistical significance.

P55 Predictors of flexible ureteroscope instrument repair: analysis of the last 2 years at the University Hospital Zurich

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Introduction:

Flexible ureteroscopes are prone to damages. This study aims at evaluating procedural lifespan and hazards causing instrument repair.

Methods:

All patients undergoing ureteroscopy (URS) between January 2018 and December 2019 were retrospectively identified. Medical charts were reviewed for data extraction. Only patients undergoing flexible URS were considered for analysis. Primary outcome was need for instrument repair after surgery.

Results:

At total of 586 patients were identified. Of these, 486 patients (83 %) underwent flexible URS and were considered for analysis. Combination with percutaneous nephrolithotomy was found in 13 patients (3 %). Indication for surgery was stone disease in 397 (82 %), tumor in 57 (12 %), or other in 32 (7 %). Median age was 53 years (range 20 – 93). Male/female ratio was 2.03. Left/right side ratio was 1.25, with 30 bilateral cases (6%). Resident/senior operator ratio was 1.09. Lower pole URS was reported in 205 (42 %). Median operative time was 75 minutes (range 7 – 258). Ancillary device use was as follows: ureteral access sheath in 285 (59 %); laser fiber in 258 (53 %); basket in 352 (72 %). A total of 44 flexible URS needed to be sent for repair after surgery, resulting in a mean 11 interventions per instrument. Median instrument service time was 5 months (range 0.5 – 15). Univariable analysis revealed significant predictors for instrument repair: operative time (OR 1.31 for every additional 30 minutes; 95% CI 1.08 – 1.59; $p = 0.007$), lower pole URS (OR 2.12; 95% CI 1.13 – 4.00; $p = 0.038$) and laser fiber use (OR 2.01; 95% CI 1.04 – 3.90; $p = 0.04$). On multivariable analysis, only operative time was an independent significant predictor for instrument repair.

Conclusions:

In an academic setting, each single flexible URS performs a mean 11 interventions until need for instrument repair. Operative time, lower pole URS and laser fiber use seem to be predictors of instrument repair.

P56 Detection of microbial colonization of the urinary tract of patients prior to secondary ureterorenoscopy is highly variable between different types of assessment: results of a prospective observational study.

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This study compares the findings of different detection methods for microorganisms in patients with ureteral stents undergoing secondary ureterorenoscopy including the use of a novel validated examination pipeline for biofilms on ureteral stents. Of the included 94 patients, 21.3% showed bacteriuria in preoperative urine cultures. Intraoperative urine culture showed bacteriuria in four (4.3%) of the patients. Stent biofilm cultures were positive in 12.9% and qPCR detected bacterial DNA in 18.1%. The findings of the different examinations were poorly correlated with each other. Detection of microorganisms in the urinary tract of patients with indwelling ureteral stents is highly dependent on timing (i.e. pre- vs intraoperative) and method of assessment. Preoperative routine urine cultures are not predictive for intraoperative urine- and stent culture. These results cast doubt on the clinical relevance of enterococcal species, staphylococci, and streptococci if identified preoperatively prior to stent removal. The timing of oral preoperative antibiotic prophylaxis might need to be reconsidered.

P57 Reduction of stent-associated morbidity by minimizing stent material: A prospective, randomized, single-blind study assessing a customized "Suture-Stent"

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Purpose

After introducing a new concept of stent design by replacing the distal ureteral part with a suture, we compare this Suture-Stent to the standard ureteral stent in patients with urolithiasis requiring stenting as preparation for secondary URS.

Materials and Methods

Patients with unilateral urolithiasis above the iliac vessel crossing requiring stenting in preparation for secondary URS were randomized to a standard ureteral stent or Suture-Stent. The stent remained in place until the secondary URS (2-6 weeks later). The USSQ and an additional questionnaire were completed after one week, at the time of the URS and 2-6 weeks later without an indwelling stent. Stent safety and adverse events were assessed during the whole study period.

Results

A total of 88 patients were randomized to treatment. Patients treated with the Suture-Stent reported significantly lower urinary symptoms score one week after stent insertion (mean 13.7 vs. 7.1, $p < 0.001$), corrected for baseline symptoms (USSQ at final visit without indwelling stent). At the time of secondary URS, urinary symptoms (mean 12.2 vs. 4.7, $p < 0.001$) and pain subscores (17.6 points vs. 4.7, $p = 0.004$) were significantly lower in the Suture-Stent group. Similar results were seen for urinary symptoms and pain when not corrected for baseline values. Secondary URS was successfully performed in all patients studied. Adverse events were rare (15/88) and similarly present in both groups.

Conclusions

Replacement of the distal part of ureteral stents by a suture can significantly reduce stent-associated symptoms without restrictions regarding secondary stone removal or safety aspects.

P58 Urinary stone location with ureteral stents in place: always on the move, and not where you would expect

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Introduction:

Whilst it is well established that small stones can pass with a ureteral stent in place, there is still very little scientific understanding of the migration process of urinary stones with indwelling ureteral stents in place. The objective of this study was to assess the migration of urinary stones with indwelling ureteral stents, and assess the role of stone size, location and composition.

Methods:

We performed a retrospective analysis of stone characteristics and positions in patients treated with secondary retrograde intrarenal surgery (RIRS) for symptomatic urinary stones between January 2015 and 2019 at our institution. Stone location was assessed at the time of ureteral stent insertion and three to four weeks later before the planned stent removal and RIRS. For each of the two time points, stone position was classified as one of six positions on the pathway from the kidney to the bladder, and the proportion of stones found at each position was determined. For the analysis of stone migration, the positions were pooled to distinguish three main parts (kidney, proximal, distal). The proportion of stones staying in place, and of stones with cranial or caudal migration was determined.

Results:

A total of 393 patients were included, the median age was 53.0 years and the median stone size was 7 mm. At initial presentation, 40% of stones were located in the kidney, 30.4% in the proximal ureter, 22.5% in the distal ureter, while 7.2% of the stones were located at one of the three sites of narrowing. When considering individual transitions, 66.9% of the stones stayed in place, 29% moved caudally (mostly from the kidney) and 4.1% moved cranially (mostly from distal positions, most likely attributed to a push-back phenomenon). In regard to stones located at a site of anatomic narrowing, this proportion increased significantly to 18.8% at the time of stone extraction. The mean size of stones depended significantly ($p < 0.001$) on their initial position, with the largest stones seen in the kidney and on the type of migration: For any given initial position, stones with caudal migration were smaller.

Conclusion:

Our study further supports the notion of urinary stone migration with a ureteral stent in place, and demonstrated that smaller stones are more likely to migrate caudally. Furthermore, we were able to demonstrate that urinary stones are more than twice as likely to be found at a site of anatomic narrowing, when a ureteral stent is in place.

P59 Intravesical ureteral stent position is highly variable over time and with patient position: an analysis of 1466 radiographic images

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Purpose

To investigate the variability of the intravesical position of distal ureteral stents over time and depending on patient positioning.

Materials and Methods

Radiographs of patients who underwent ureteral stent insertion and secondary ureterorenoscopic stone removal between January 2015 and January 2019 were assessed retrospectively. Distal ureteral stent loop position (ipsilateral; crossing midline; contralateral) was recorded in lithotomy position (LP) at the time of stent insertion and removal and in supine position (SP) in between. We analyzed the frequency of stent position changes and whether they depend on ureter length, stone size or stone location.

Results

A total of 1'466 radiographic images of 572 patients were analyzed. When comparing imaging performed over time in LP, a change in distal ureter stent position was seen in 42% of the patients. Stents mainly shifted from ipsilateral towards contralateral position. A stent position change between SP and LP was seen in 50.3% of the patients. In general, discrepancies between ureter length and stent length did not appear to influence the frequency of position changes, nor did stone size or stone location. Conversely, the probability of a stent being in ipsilateral position at one or several assessments increased with a longer ureter and with a shorter stent.

Conclusions

The intravesical position of the ureteral stent is highly variable over time and depending on patient positioning. This raises questions regarding the reliability of the initial radiographic assessment of stent position and has implications for further studies assessing the influence of stent position on stent-associated morbidity.

P60 Traitement endoscopique des reflux vésico-urétéraux symptomatique chez les patient greffés rénaux

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Contexte et objectif :

Nous évaluons le succès d'un traitement endoscopique, mini-invasif du reflux vésico-urétéral symptomatique après transplantation rénale et les facteurs prédictifs de succès.

Matériel et méthode :

Nous avons inclus rétrospectivement 21 patients, 12 femmes et 9 hommes, et 22 unités rénales, présentant un reflux vésico-urétéral (grade 1-5) symptomatique entre septembre 2016 et février 2020. Le reflux a été documenté par une cystographie rétrograde et mictionnelle. Ils sont considérés symptomatiques en cas de pyélonéphrite aigüe du greffon, altération de la fonction rénale ou infections urinaires basses récidivantes. Le traitement consiste à une injection de Dextranomer/hyaluronic acid copolymer (Deflux®) (DX/HA) autour du méat urétéro-vésical du greffon. L'évaluation post-opératoire est clinique et chez la plus part des patients également radiologique par cystographie. Le succès clinique est défini par l'absence de pyélonéphrite aigüe du greffon, stabilité de la fonction rénale après injection de DX/HA copolymer (Deflux®). Une analyse statistique par test exact de Fisher a été réalisée pour déterminer l'influence de facteurs sur le succès de l'injection.

Résultats

L'âge médian est de 57 ans et le temps moyen entre la greffe et l'injection est de 63 (5-387) mois. Le taux de succès après la première injection est de 45% et 68% après la seconde injection. 6 patients ont eu deux injections de DX/HA copolymer (Deflux®), 3 patient ont eu 3 injections et 4 patients ont eu une anastomose urétéro-urétérale après échec d'une ou plusieurs injections. Un patient a présenté une pyélonéphrite obstructive post-opératoire ayant nécessité la mise en place d'une pigtail. 3 autres patients ont nécessité également la mise en place d'une pigtail pour une urétéro-hydronephrose sur obstruction. Le sexe, l'âge, le nombre de cc injecté, la présence d'un méat béant ou non, le diabète et le nombre de mois entre la greffe et l'injection ne sont pas révélés comme des facteurs pronostic de succès. Par contre le grade de reflux actif était significativement associé à la réussite de l'injection ($p = 0.009$).

Conclusions

Le traitement endoscopique pour des reflux vésico-urétéraux symptomatique post greffe rénale est une procédure faisable. Elle est efficace pour plus de 2/3 des nos patients. Au vu d'un abord mini-invasif et une faible morbidité, celle-ci pourrait devenir une attitude thérapeutique de première intention.

P61 Manageable risk factors for acute kidney injury after robotic partial nephrectomy

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Aims

Acute kidney injury (AKI) following laparoscopic robot-assisted partial nephrectomy (RAPN) emerged as a major risk factor for long-term estimated glomerular filtration rate (eGFR) decrease. In this retrospective analysis, we investigated the association of manageable and given risk factors with postoperative AKI.

Materials & methods

All patients who underwent RAPN at our institution since 2011 were included. We calculated eGFR using the Kidney Disease Improving Global Outcomes (KDIGO) guidelines. The primary outcome AKI was defined according to the Risk Injury Failure Loss End-stage (RIFLE) criteria from pre- to postoperative values until patient's discharge. The secondary outcome was significant long-term (> 3 months) eGFR reduction, which was defined as $\geq 25\%$ from baseline eGFR, according to previous reports. We calculated the ischemia time thresholds for warm ischemia and selective clamping using the Youden index. Uni- and multivariable logistic regression analyses were used to examine predictors of AKI. We used Cox proportional hazard regression models to investigate prognostic factors for significant long-term eGFR reduction. The local review board gave ethic approval.

Results

Overall, 154 patients with a median age of 65 (interquartile range 57-75) years were eligible for analysis. Thirty-three (21.4%) patients experienced postoperative AKI. During a median follow-up of 19.7 months, 28 (18.2%) patients developed significant long-term eGFR reduction. Among all RAPNs, 90 (58.4%), 43 (28.0%) and 21 (13.6%) were performed with warm ischemia, selective clamping, and zero ischemia, respectively. Multivariable logistic regression analyses, adjusted for RENAL score and female gender, revealed that selective clamping ≤ 29 min (Odds ratio [OR] 0.12, $p=0.002$), warm ischemia time ≤ 17 min (OR 0.10, $p < 0.001$) and zero ischemia time (OR 0.10, $p=0.035$) significantly reduced the risk of postoperative AKI. In multivariable Cox regression analysis, AKI was the strongest prognostic factor (HR 6.6, $p < 0.001$) for significant long-term eGFR reduction.

Conclusions

This study confirms that postoperative AKI is of utmost importance for long-term prognosis of functional outcomes following RAPN. Intraoperative clamping techniques seem to have the potential to reduce the risk of AKI when performed within time thresholds and could therefore improve long-term eGFR outcomes.

P62 Robot-Assisted Laparoscopic Ureteral Reimplantation: very often successful, which type of failures?

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Introduction

Robot-assisted laparoscopic ureteral reimplantation (RALUR) has been standardized over the last years. However its long-term success rate has been seldom reported. We report our long-term follow-up, focusing on the type of failures.

Methods

Retrospective review of all consecutive RALUR between April 2007 and February 2019 at our institution. The indications included ureteral stricture (38), vesico-ureteral reflux (4), uretero-vaginal fistula (3) and iatrogenic ureteral section or disjunction (3). Follow-up consisted of clinical examination, serum creatinine measurement and renal ultrasound, CT or Lasix scan. Patient and operative demographics were analyzed. RALUR was performed by three experienced surgeons.

Results

48 patients (female 39, male 9) had RALUR, with a mean age of 51 years. Site of the ureteral stricture was iliac (5) and pelvic (33). Mean ureteral stricture length was 2.8 ± 0.6 cm. Stricture etiologies were gynecologic surgery (16), endoscopic surgery (TURB 2, ureteroscopy 3), neoplasia (urothelial carcinoma 4, metastatic breast cancer 2, lymphoma 1), endometriosis (6) and miscellaneous (4). A non-refluxing anastomosis was performed in 28 patients (58%). Mean operative time was 239 ± 22 minutes. Mean increase in creatinine level was insignificant (0.6 ± 5.3 $\mu\text{mol/l}$). Mean postop hospital stay was 4.5 ± 0.6 days. Median follow-up was 34 months. Forty patients (83%) had successful outcome, while 8 (17%) recurred (VUR 1, ureteral stricture 7), with a median time to recurrence of 11.5 months (IQR 4-19). Two recurrences required open surgery (VUR 1, stricture 1) while 3 were managed by endoscopic ureteral dilatation & endoureterotomy. Recurrent strictures occurred in 5 of 7 neoplastic (71%), 3 of these requiring indwelling ureteral stenting. Ureteral stricture recurrence took place in 3 iliac strictures (60%) vs. 4 pelvic strictures (12%; $p = 0.01$). Initial ureteral stricture length was significantly longer in the recurrent ureteral stricture group (4.7 cm vs. 2.4 cm; $p = 0.001$). Ureteral stricture recurrence occurred in 5 psoas hitch reimplantations (19%), 1 direct reimplantation (8%) and 1 Boari flap reimplantation (13%). One out of these 7 procedures had a non-refluxing anastomosis. Clavien grade 3 complication rate was 8.3%. There were no grade 4 or 5 complications.

Conclusions

Long-term minimally invasive reimplantation was successful. Recurrences were more frequent in long and iliac strictures, so as in neoplastic etiologies.

P63 Feasibility of day care surgery for robot-assisted onco-urologic procedures

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Context:

Mini-invasive surgery has efficiently reduced post-operative length-of-stay after various onco-urological procedures. Our purpose was to study the feasibility and safety of robot-assisted radical prostatectomy (RARP) and partial nephrectomy (RAPN) as an ambulatory procedure for selected patients.

Methods:

Data were collected as an observational cohort from 2018 to 2019. Inclusion criteria were patients with a good performance status and a Charlson score < 5. Exclusion criteria were presence of any coagulopathy or contra-indications to outpatient surgery (e.g. living too far from hospital or alone). For patients undergoing RAPN, another inclusion criteria was a RENAL score between 4-6, indicating a low complexity renal mass to remove. Procedures were performed as the initial morning case with a team dedicated to outpatient surgery. Anesthesia protocols used allowed quick recovery and rapid discharge from the hospital. A follow-up call from the paramedical staff was systematically done the day after surgery to enquire about any unusual complaint or early complication. Peri-operative outcomes and complications according to the Clavien classification were collected. Follow-up consultation at one month was carried-out with assessment of patient-reported general satisfaction.

Results:

38 patients underwent RARP (n=18) or RAPN (n=20) as an outpatient procedure. Median age was 63 yo (57–64) and median BMI 24,5 (23,7–26,2). Three intraoperative adverse events were reported, requiring the stay overnight. 35 patients were able to be discharged home after a median post-operative monitoring time of 350 min. Two procedures were followed by an unplanned readmission due to early complications within the first 30 days, one Clavien I (pain and anxiety) and one Clavien IIIa (hematoma with active bleeding requiring embolization at day 3). This translates into an outpatient success rate of 87%. Due to the small size of our cohort, no peri-operative predictor of outpatient failure was identified. All patients were satisfied by the outpatient pathway and more than 90% of them would recommend the same type of management to someone else.

Conclusion:

RARP and RAPN are feasible as an outpatient procedure without major perioperative morbidity for selected patients. Patients satisfaction is high. The benefit of such an outpatient pathway for the patient, the putative economic benefit related to the decrease in hospital stay, presently under study, remains to be demonstrated.

P64 A comparison of perioperative outcomes of laparoscopic versus open nephroureterectomy for upper tract urothelial carcinoma: a propensity score matching analysis

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Objective:

To compare perioperative outcomes of open versus laparoscopic RNU.

Materials and methods:

We evaluated a multi institutional retrospective database composed by 1512 patients diagnosed with UTUC and treated with laparoscopic or open RNU between 1996 and 2016. Perioperative outcomes included operative time, blood loss, and length of hospital stay, as well as postoperative complications, readmission, reoperation, and mortality rates at 30 and 90 days from surgery. To adjust for potential baseline differences between the two treatment groups, a propensity score matching was performed using preoperative parameters such as: age, gender, body mass index (BMI), and American Society of Anesthesiologists (ASA) score.

Results:

Overall, 1007 (66.6%) patients were treated with open and 505 (33.4%) with laparoscopic RNU. In the whole cohort, open RNU resulted into shorter median operative time (195 vs 217 minutes, $p < 0.001$), but superior median blood loss (328 ml vs 270 ml, $p < 0.001$), and median longer hospital stay (11 vs 9 days, $p < 0.001$) in comparison to laparoscopic RNU. No statistically significant difference was identified for the other variables of interest (all p values > 0.5). After propensity score matching, at multivariable analysis laparoscopic RNU resulted in longer operative time (Hazard Ratio (HR) 3.09, 95% Confidence Interval (CI) 1.90-5.04, $p < 0.001$) and shorter hospital stay (HR 0.32, 95% CI 0.23-0.45, $p < 0.001$) compared to open RNU, but the risk of complications, readmission, reoperation, and mortality rates at 30 and 90 days from surgery remained similar between the two treatment modalities (all p values > 0.5).

Conclusion:

Laparoscopic RNU is associated with shorter hospital stay, but longer operative time in comparison to open RNU. Otherwise, there were no differences in other perioperative outcomes between these surgical modalities even after propensity score matching. Given the similar safety profile between open and laparoscopic RNU, the choice between these surgical modalities should be based on other criteria.

P65 Outcomes and characteristics of patients after radical surgery of upper tract urothelial carcinoma

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OBJECTIVE:

To describe outcomes and characteristics of patients undergoing radical surgery of upper tract urothelial carcinoma (UTUC) and evaluate risk factors for intravesical recurrence (IVR).

PATIENTS AND METHODS:

Our retrospective, single-center consecutive analysis, included 77 patients undergoing radical surgery (radical nephroureterectomy (RNU) vs. segmental ureterectomy (SU)) of UTUC between 2009 and 2019. Clinical and pathological characteristics, risk factors were analysed and compared with patient outcomes.

RESULTS:

In our cohort (n=77), male to female ratio was 2:1, median age at surgery was 68 years (36-90). History of tobacco consumption was noted in 52% of patients and at diagnosis, hydronephrosis was present in 70%. Multifocality was present in 13% of the cases. All patients underwent radical surgical resection (66% RNU vs 34% SU) with the following pathological results: (pT0) in 3/77 (4%) patients, organ confined tumor (pTa-2) was present in 45/77 (59%) and non-organ confined (pT3+) in 28/77 (37%). Concomitant carcinoma in situ, LVI and high-grade features were present in 29/77 (38%), 30/77 (39%), 60/77 (78%) of the patients, respectively. The 3-year cancer specific survival (CSS) was 69% and 3-year overall survival (OS) was 57%. Intravesical recurrence (IVR) occurred in 40/77 (52%) patients with a median time to recurrence of 23 months (3-116). Only history of smoking was associated with IVR (Smokers 24/40 (60%) vs. non-smokers 15/37 (41%); $p = 0.04$). Surgical approach (RNU vs. SU) was not associated with IVR but open surgery was associated with lower rates of IVR compared to laparoscopy ($p = 0.04$). The Kaplan-Meier survival analysis showed better outcomes in patients without IVR compared to patients with IVR (CSS: 86% vs. 63%, $p = 0.2$; OS: 71% vs. 51%, $p = 0.14$), however, this difference did not reach statistical significance.

CONCLUSIONS:

In line with the literature, IVR after radical treatment of UTUC occurred in 50% of the patients. Smoking history as well as laparoscopic surgery are associated with higher rates of IVR. Although not statistically significant, IVR seems to decrease patient outcomes. Regular follow-up is important after radical treatment of UTUC for the detection of IVR. Counseling about smoking cessation should be offered to patients with UTUC.

P66 Diagnostic value of urine cytology in pharmacologically forced diuresis for diagnosis and follow-up of upper tract urothelial carcinoma

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OBJECTIVE:

Knowing the diagnostic accuracy of a test is fundamental for a rational use in the clinical practice. Urine cytology analysis of a pharmacologically forced diuresis (UCFD) can be used for evaluation of upper tract urothelial carcinoma (UTUC) as diagnostic tool and as follow-up method. In this study we aim to evaluate the value of UCFD for both purpose.

METHODS:

To evaluate the diagnostic value of UCFD, we enrolled a first consecutive cohort of 77 patients with UTUC treated with radical surgery between 2009 and 2019. In 30/77 43% patients UCFD was preoperatively performed. A second cohort (n=1005) of patients underwent RC in a curative intent due to bladder cancer from 2000 to 2017. UCFD was performed as follow-up of the upper urinary tract (UUT) in 598/1005 patients (60%). High-grade urothelial carcinoma cells in UCFD was considered as positive.

RESULTS:

In the first cohort, 17/30 (57%) had muscle-invasive UTUC. High- and low-grade UTUC were found in 28/30 (93%) and 2/30 (7%), respectively. Concomitant carcinoma in situ was present in 10/30 (33%) of patients. Sensitivity of UCFD in patients with invasive, high-grade, low-grade and concomitant CIS was 12%, 10%, 0%, 20%, respectively. In the second cohort, a total of 1560 UCFD were analyzed, and 35/1560 (2.2%) were positive. UUT recurrence was present in 13/35 (37%) cases and the remaining 22/35 (63%) cases had urethral recurrence. In 3 patients with negative imaging, UCFD identified cancer recurrence in the UUT. Overall, 33 patients had radiological proven recurrence in the UUT during follow-up. In 26/33 patients UCFD was analyzed prior to curative or palliative treatment, and was positive in 13/26 (50%) patients. As follow-up tool, UCFD showed a sensitivity, specificity and positive predictive value of 50%, 100% and 100%, respectively.

CONCLUSIONS:

Urine cytology obtained from forced diuresis is a simple and non-invasive diagnostic method. As diagnostic tool, sensitivity is slightly better in patients with invasive UTUC and concomitant carcinoma in situ. For follow-up, positive UCFD was diagnostic and could even reveal cancer recurrence in the urethra in cases with orthotopic bladder substitute. Although UCFD may add diagnostic value in cases with recurrence of carcinoma in situ, the need for more reliable biomarkers for the follow-up and diagnosis of the UTUC remains.

Posterdiskussion V – Grundlagenforschung

Discussion des posters V - La recherche fondamentale

P67 Heterogeneity of DNA ploidy as a hallmark of clonal evolution in prostate cancer

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Introduction

In this study, we investigate DNA ploidy among morphologically distinct tumor populations, elucidating aneuploidy as a hallmark of genomic instability and a driver of tumor heterogeneity.

Methods

We defined morphological criteria for the distinction of diploid-like and aneuploid-like subpopulations within the same prostate cancer in radical prostatectomy specimens from six patients. To assess the ploidy status with different methodological approaches, we performed DNA-cytometry and SISH (silver in-situ hybridization) for three different centromere probes. The clonal relationship of the subpopulations was examined by arrayCGH (array comparative genomic hybridization). Additionally, we used immunohistochemistry to determine the status of ERG, ALDH1A1, and Ki67 these distinct subpopulations.

Results

Morphological categorization in diploid-like was consistent with DNA content assessed by DNA cytometry and/or SISH. Median Ki67 expression was 10% (range 5-20%). All examined tumor populations were ERG negative. Intriguingly, arrayCGH revealed a high clonal relationship between the diploid-like and the aneuploid-like populations. This was accompanied by an enrichment of ALDH1A1 expression in the diploid-like population. This strongly indicates that the aneuploidy-like populations derived from the diploid populations. We also saw clonally independent diploid and aneuploid-like tumor populations within one tumor.

Conclusion

By morphological assessment, we were able to distinguish diploid tumor populations within aneuploid tumors. Some of these were enriched for the ALDH1A1 stem cell marker as a potential source of progression and therapy resistance. Regarding the genealogy of intratumor heterogeneity, we found independent foci as well as closely related subpopulations in which aneuploidy emerged during clonal evolution.

P68 Phenotypic and morphological characterization of patient-derived bladder cancer organoids

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Background and objectives:

Patient-derived organoids (PDOs) better reflect the molecular and cellular complexity characterizing bladder cancer (BC) as compared to other in vitro models. The combination of these three-dimensional (3D) models with advanced fluorescence imaging technologies such as light-sheet microscopy may unlock new strategies to study BC biology and treatment response. Hence, here we aimed at generating BC PDOs and developing methods to characterize their phenotype and 3D morphology at a high resolution.

Material and Methods:

To generate PDO lines, we used fresh clinical samples obtained from BC patients undergoing transurethral resection of bladder tumor (TURB, n=11). Immediately after surgery, tissue specimens were evaluated to determine quality and tumor content and processed for organoid culture. Detailed phenotypic analysis through standard histological characterization and immunofluorescence analysis was performed in patient samples and their matched PDOs. In addition, we optimized methods to clear and immunostain organoids while maintaining their 3D structure (i.e., pre-processing step), thus enabling the acquisition of high-resolution 3D images with light-sheet microscopy.

Results:

PDO lines were successfully established and maintained for a maximum of 30 days in culture, before analysis and/or passaging. PDOs recapitulated histological features and exhibited patterns of expression of luminal and basal markers (i.e., CK8 and CK5, respectively) reminiscent of the original samples. Light-sheet imaging allowed to acquire high-resolution 3D images and extract phenotypic data from the generated PDOs. In particular, we closely investigated the distribution of CK5+ and CK8+ cells within the 3D PDO structures; as an example, in a PDO line with “mixed” phenotype, CK5+ cells were homogeneously distributed on the organoids’ surface, while CK8+ cells appeared to cluster in specific areas. Next, we will assess the significance of these preliminary findings in additional PDO lines.

Conclusions:

Cancer progression and response to therapeutics are known to be strongly influenced by cellular phenotypic features and 3D spatial organization. The combination of the organoid technology with light-sheet microscopy therefore represents a promising tool to elucidate mechanisms underlying bladder cancer biology and treatment response.

P69 Dissecting cancer stem cell-associated phenotypic heterogeneity and its relevance in prostate cancer progression

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Background and Objectives:

The relevance of stem-like cell populations for the development of castration-resistance in prostate cancer (PCa) patients is poorly understood. Here we aimed to comprehensively analyze the dynamic of putative stem cell populations in the transition from hormone-naïve (HN) to castration-resistant (CR) PCa.

Materials and Methods:

Expression of eight stemness-associated markers (ALDH1A1, ALDH1A3, ALDH3A1, BMI1, NANOG, NKX3.1, OCT4, SOX2) was first assessed by immunohistochemistry in a tissue microarray (TMA) comprising 112 matched HN and CR tissues specimens, derived from 55 PCa patients and associated with detailed clinic-pathological data. Unsupervised clustering analysis was performed to stratify patients according to the expression of the eight CRSC markers. To simultaneously assess the expression of multiple markers, we designed a custom-made panel of >25 antibodies, allowing for single-cell multiplexed protein analysis in situ using the CODEX (Co-Detection by IndEXing) technology.

Results:

While expression of particular stem markers was dynamic over time in some patients, none of them showed significant changes in expression upon the development of castration resistance ($p > 0.05$, CR vs. HN). Nevertheless, cluster analysis identified phenotypic subtypes based on the expression of specific stem-associated markers, with one particular cluster associated with shorter time to castration-resistance. To decipher quantitative expression of multiple markers at single-cell level and localization of distinct cell populations in situ, we designed and optimized a comprehensive antibody panel amenable to the CODEX technology. In particular, our custom-made panel included antibodies recognizing markers of PCa stem-like cells and prostate epithelial subtypes, cancer-associated markers, and basic markers of the tissue microenvironment.

Conclusions:

Our findings indicate stemness-associated patterns that are associated with the development of castration-resistance. Next, we will use CODEX to quantify and elucidate the spatial distribution of putative PCa stem cells and the cells located in their immediate proximity (i.e., presumably composing their niche), in matched HN and CR specimens. We anticipate to pinpoint cellular and phenotypic changes associated with castration-resistance that may represent novel prognostic and/or predictive biomarkers.

P70 Optimizing clinical trial design using prospective cohort study data: a case study in neuro-urology

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Background and objectives:

Prospective cohort data can provide relevant information for the design and planning of randomized controlled trials (RCTs). The objective of this study is to illustrate how cohort data can be employed in RCT planning to assess feasibility and operational challenges, using the TASC trial (Transcutaneous tibial nerve stimulation in patients with Acute Spinal Cord Injury to prevent neurogenic detrusor overactivity: a nationwide randomized, sham-controlled, double-blind clinical trial) as a case study.

Materials and methods:

TASCI is nested in the multicenter Swiss Spinal Cord Injury Cohort Study (SwiSCI), which prospectively includes patients with acute spinal cord injury. In simulations, data from 640 patients, collected by SwiSCI, were used to investigate different scenarios of patient eligibility and study consent, as well as the performance of the randomization list. Descriptive analysis was used to describe the population of interest and the simulation results, multivariable logistic regression analysis was performed to identify predictors of discharge within the TASC intervention time period.

Results:

The recruitment target of 114 patients is obtainable within the originally envisioned three-year time period under the most favorable recruitment rate scenario examined. The distribution of the primary prognostic factor produced imbalance in the randomization lists and informed further discussion of the cut-off values used in stratification. Observed waves of patient admissions resulted in overlapping intervention periods for multiple participants, which guided resource allocation. Early discharge was related to the primary prognostic factor and study center, but is only anticipated in about 8% of participants.

Conclusions:

Purposive analyses of cohort data in the trial design phase can provide proof of concept evidence about trial feasibility, as well as provide support for decisions regarding the investment and allocation of resources. However, the reality-check offered by piloting is still

a necessary part of the implementation phase of the RCT, as assumptions can be further investigated and adjustments can be made. This case study demonstrates that prospective cohort data are a valuable resource for informed planning of an RCT.

P71 Impact of myostatin inhibitor on smooth muscle regeneration

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Introduction and objectives:

Tissue engineering therapies utilizing smooth muscle regeneration may provide alternative treatments for diseases such as bladder dysfunction, urinary incontinence and erectile dysfunction. Smooth muscle cells (SMCs) are the main component of the bladder detrusor muscle. Myostatin is a negative regulator of muscle growth. Myostatin inhibitors are used in clinical trials as a therapy for skeletal muscle diseases but the role and the expression pattern of myostatin has not been reported yet within bladder SMCs. Thus the goal of our research is to improve the SMCs quality and quantity by inhibiting myostatin with suramin, a polyanionic compound that prevents TFG- β 1's from binding to their receptors. For this purpose, we investigated the expression pattern of myostatin gene and protein in human and rat bladder SMCs. Furthermore, we examined, if a combination of myostatin with its inhibitor suramine could further increase the cell proliferation and cell number.

Materials and Methods

Human and rat bladder derived SMCs were isolated and characterized. SMCs were cultured in the presence and absence of suramin (0-50 μ g/ml), a pharmacological inhibitor of myostatin and myostatin protein (0-150 ng/ml). Cells proliferation was evaluated by WST-1 assay. The impact of suramin or/and myostatin treatment on rat SMCs gene and protein expression was analyzed by Real-Time PCR and Western Blot.

Results

Myostatin expression was detected in human and rat SMCs at RNA and protein level. Treatment with suramin 20 μ g/ml significantly increased the rat bladder SMCs cell proliferation. Furthermore, treatment with suramin 50 μ g/ml inhibited in the expression and signaling of myostatin and inhibited the expression of MYH11 contractile protein in rat bladder SMCs. Preliminary data from human bladder SMCs cell proliferation assay also suggest a positive impact of suramin in human cells.

Conclusion

Our study demonstrates for the first time that myostatin is expressed in bladder SMCs. In addition, suramin improves bladder SMCs proliferation. This study indicates that suramin is a myostatin inhibitor that may have a tissue engineering therapeutic potential for patients with urinary incontinence.

P72 Stroma transcriptomic and proteomic profile of prostate cancer metastasis xenograft models reveals conservation of bone microenvironment signatures

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Introduction & Objectives:

Resistance acquisition to androgen deprivation treatment and metastasis progression are a major clinical issue associated with prostate cancer (PCa). The role of stroma during disease progression is insufficiently defined. We investigated how PCa tumors predispose their microenvironment (stroma) towards specific gene expression patterns.

Materials & Methods:

Transcriptomic and proteomic analyses were performed on differentially aggressive patient derived-xenografts (PDXs). RNA sequencing and mass spectrometry were performed on the PCa PDXs BM18 (castration sensitive) and LAPC9 (castration resistant) representing different disease stages. Using organism-specific reference databases, the human-specific transcriptome (tumor), was identified and separated from the mouse-specific transcriptome (stroma). To identify proteomic changes in the tumor (human) versus the stroma (mouse), we performed human/mouse cell separation and subjected protein lysates to quantitative TMT labeling and mass spectrometry.

Results:

Among the most abundant stromal genes, modulated by androgen levels in vivo and highly expressed in castration resistant LAPC9 PDX was TENASCIN C (TNC) Tissue microarray of primary PCa samples (N=210) was used to evaluate whether TNC could act as a potential metastasis prognosis marker. Low number of TNC-positive cells was associated with statistically significant clinical progression to local recurrence or metastasis, compared to the high TNC-positive group. Stroma markers of osteoblastic PCa bone metastases (Ob-BMST)1 seven-up signature (Mcam, Pdgfrb, Postn, Aspn, Fscn1, Sparcl1, Pmepa1), were induced in the stroma by the host organism in metastatic xenografts, although in a non-bone site, indicating conserved mechanisms of tumor cells to induce a stromal pre-metastatic signature.

Conclusions:

We molecularly characterised the tumor and stroma molecular profiles and demonstrated the androgen-dependency of stroma and induction of bone metastasis seven-up signature genes (Ob-BMST). Our data shows that metastatic PCa PDXs, that differ in androgen sensitivity, trigger a differential stroma response, suggesting reciprocal interactions among stroma and tumor cues.

P73 Organ-on-chip technique as a model to study cripto signaling in lethal prostate cancer

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ABSTRACT

Prostate cancer (PCa) is the most frequently diagnosed malignancy and second leading cause of cancer-specific deaths in men in Western countries. Human tumors express high levels of Cripto, an oncofetal protein. We hypothesize that Cripto could be involved in the late progression of PCa and aim to study its role in organoids derived from genetically engineered mice models of PCa cultured in an organ-on-chip microfluidic system.

INTRODUCTION

Early stages of PCa can be effectively treated with surgery and castration, but frequently the cancer becomes castration resistant (CRPC), possibly due to pre-existing stem cell-like PCa cells that survive castration in a dormant state and then reinitiate tumor growth and metastasis¹. Cripto regulates stem cell-associated signaling pathways and promotes cellular plasticity, EMT and maintenance of the stem cell stage during normal development, tissue homeostasis and tumorigenesis².

MATERIAL AND METHODS

The Nkx3.1 CreERT2; R26 LSL-YFP/ LSL-YFP animals were crossed with Pten floxed (Ptenflox/flox) and K-Ras mutant animal (KrasLSL-G12D/+) to generate NP (Nkx3.1CreERT2; Ptenflox/flox, R26 LSL-YFP/ LSL-YFP) and NPK mice (for Nkx3.1CreERT2; Ptenflox/flox; KrasLSL-G12D/+). NP animals develop high-grade PIN/carcinoma lesions with local invasive epithelium while NPK animals develop invasive prostate adenocarcinoma with lung and liver metastasis³. Organoids from prostate tissue of NP and NPK mice were derived⁴. OrganoPlate[®] Graft is an advanced microfluidic 3D culture plate provided by MIMETAS, which allow the perfusion of solid tissue in vitro.

RESULTS

We measured the expression of Cripto in a PCa TMA containing 210 PCa patients from the EMPACT5. We show that elevated number of Cripto positive cells within the primary tumor correlates with PSA ($p = 0.002$) and local/metastatic ($p = 0.00037$) progression. To assess Cripto role in early and late PCa, NP and NPK animals were treated with tamoxifen. Prostate tissue was collected, digested, FACS sorted (YFP+/-) and cultured as organoids. Currently, we are evaluating Cripto levels in NP and NPK organoids.

CONCLUSION

Human tumors express high levels of Cripto compared to their normal tissue counterparts, and poor patient Outcomes correlate with high Cripto expression⁵. For this reason, targeting signaling pathways involved in Cripto-driven CRPC is critical.

Posterdiskussion VI – Hoden

Discussion des posters VI - Les testicules

P74 A risk benefit analysis of prophylactic anticoagulation for patients with metastatic germ cell tumours undergoing first-line chemotherapy

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BACKGROUND:

In patients with metastatic germ cell tumors (mGCT) venous thromboembolic events (VTE) are recognized complications but it remains unclear which patients should have prophylactic anticoagulation. We assessed the risk of VTE before, during, and after chemotherapy in mGCT patients with and without VTE risk factors.

PATIENTS AND METHODS:

This retrospective analysis included mGCT patients treated with first-line platinum-based chemotherapy without prophylactic anticoagulation. Regression analyses were performed to identify risk factors for VTE. Simulated number needed to treat (NNT) and number needed to harm (NNH) with prophylactic anticoagulation were calculated based on hazard rates of recently published trials describing the efficacy of prophylactic anticoagulation to prevent VTEs and risk of bleeding events.

RESULTS:

From 1,120 patients, 138 (12%) had a VTE, and 6 (1%) had a bleeding event. VTE was mostly diagnosed before and during but not after chemotherapy. The cumulative VTE incidence for all patients would translate into a NNT of 44 (95% confidence interval (CI) 36-56) and a NNH of 186 (95% CI 87-506). In multivariable regression analysis the following variables remained associated with an increased risk of VTE: Khorana score over 2 (odds ratio (OR) 3.32 (95% CI 1.54-7.05), and retroperitoneal lymph nodes >3.5cm (OR 2.16 (95% CI 1.21-3.91) use of a venous access device 1.63 (95% CI 0.91-2.85). Patients with 0, 1, or 2+ of those risk factors developed VTE in 3%, 8% and 11% which translated into NNTs of 103, 37, and 28.

CONCLUSION:

VTEs are mostly diagnosed before and during but not after chemotherapy. Prophylactic anticoagulation should be considered in all men with mGCT although the decision may be guided by the number of risk factors.

P75 Clinicopathological characteristics and outcomes of patients with Mesothelioma of the tunica vaginalis testis: A Systematic Review

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Introduction

Mesothelioma is an uncommon neoplasm of mesenchymal origin arising from serosal surfaces. Especially rare are mesotheliomas of the tunica vaginalis testis (MTVT). The aim of this study was to summarize the existing literature regarding clinicopathological characteristics and treatment of localized and metastatic MTVT.

Methods We performed a systematic literature review to identify case reports and series describing patients (pts) with MTVTs.

Results

Finally, 170 publications including 30 cohort studies and 140 case reports provided data of 275 pts. Mean age at diagnosis was 57 years (SD ±19). History of exposure to asbestos was described in 35%. Histopathology included malignant MTVT in 225 pts, well differentiated papillary MTVT in 30 pts and rare subtypes in 20 pts respectively. Primary therapies included radical orchiectomy in 187 testis sparing surgery (TSS) in 51 and hemiscrotectomy in 28 pts. Local recurrence was reported in 23 pts (12%) after orchiectomy, in 9 pts (18%) after TSS and in 5 pts after hemiscrotectomy. Histopathological risk factors for metastatic disease included presence of necrosis (odds ratio (OR): 7.2, p = 0.009), high mitotic index (OR: 6.6, p = 0.012), larger tumor size (OR: 2.8, p = 0.008) and local recurrence (OR: 19.9, p < 0.001).

Adjuvant chemo- and radiotherapy was performed in 16 and 19 pts, respectively. In 49 pts an adjuvant inguinal, retroperitoneal or pelvic lymphadenectomy was performed and in 19 pts (39%) histologic workup revealed cancer positive lymph nodes.

Metastatic disease was diagnosed in 31% (85/275). The most affected sites of metastasis included the retroperitoneal lymph nodes (LN) (36), lungs (29), inguinal LN (24), peritoneal surfaces (18), pleura (10), skin (10), liver (8), pelvic LN (7) and bones (7). In the metastatic setting retroperitoneal and inguinal LN dissection was performed in 6 and 7 pts, respectively. Complete response after first-line chemotherapy was reported in two cases after 6 cycles of adriamycin and cyclophosphamide or cisplatin and pemetrexed. Median survival in pts with metastatic disease was 18 (IQR 25) months.

Discussion

MTVT is a rare disease with no existing standard treatment recommendations. Radical surgery seems to offer the best chance of cure for pts with localised disease. Collaborative trials should be established to define the best diagnostic and therapeutic strategies.

P76 Clinicopathological characteristics, risk factors and outcomes of patients with para-/testicular sarcoma: a systematic review

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Introduction

The aim of this study was to summarize the existing literature of para-/testicular sarcoma. Methods We performed a systematic literature review to identify reports describing patients (pts) with para-/testicular sarcoma.

Results

398 publications provided data of 1358 pts from which data of 593 individual pts was available. Mean age for rhabdomyosarcomas and non-rhabdomyosarcomas was 16 (SD 10) and 56 (SD 20) years respectively. Reported primary therapies included orchiectomy in 1055, testis sparing surgery in 209, hemiscrotectomy in 67 and hydrocelectomy in 7 pts. Local recurrence was observed in 159 pts (11.7%) after a median of 12 months. Adjuvant inguinal/retroperitoneal/pelvic lymphadenectomy was reported in 211 pts of which 32 had positive lymph nodes. Adjuvant chemo- and radiotherapy was performed in 335 and 169 pts. Metastatic disease at any time point was diagnosed in 76/180 (42%) with rhabdomyosarcoma and in 87/263 (25%) with non-rhabdomyosarcoma ($p < 0.01$). Risk factors for metastases included larger tumor size (OR 1.03 per mm) in rhabdomyosarcoma and older age (OR 1.05 per year) and presence of necrosis (OR 4.4) in non-rhabdomyosarcoma. Compared to well differentiated liposarcoma (4.8%) all other histologies had a higher risk of metastatic disease: dedifferentiated liposarcoma (33.3%, OR 10.3), leiomyosarcoma (23.2%, OR 6.4), alveolar rhabdomyosarcoma (60.7%, OR 26.3), embryonal rhabdomyosarcoma (40.0%, OR 13.8), undifferentiated pleomorphic sarcoma (35.3%, OR 11.3) or other rare sarcomas (32.1%, OR 10.1).

Reported location of metastases included lymph nodes (LN) [retroperitoneal LN (142), inguinal LN (32), pelvic LN (22), mediastinal LN (17)], lung (87), bone (30), peritoneal surfaces (29), liver (18). In the metastatic setting retroperitoneal and pelvic LN dissection was performed in 58 and 8 pts. Complete and partial response to first-line chemotherapy was observed in 20 and 17 pts, respectively. Response was seen in all histological subtypes. Mean time from diagnosis to death for rhabdomyosarcoma and non-rhabdomyosarcoma was 19 and 30 months respectively ($p=0.2$).

Conclusion

Our series represents the largest collection of pts with para-/testicular sarcoma which identifies several risk factors for adverse outcomes and confirms the overall poor prognosis. Although no standard treatment recommendations exist, we recommend wide surgical excision and to discuss further therapies within interdisciplinary teams.

P79 Additional epididymis resection during hydrocele resection: Is it of any benefit in comparison to simple hydrocelectomy?

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Introduction:

Open hydrocelectomy via scrotal incision is the standard approach for idiopathic hydroceles (IH). Traditionally, many urologists here offer hydrocelectomy and additional resection of the epididymis in men with IH when family planning is concluded. It is believed that additional epididymis resection reduces the postoperative recurrence rate of hydroceles. However, no retrospective or prospective data does support this theory. In this study we aim to compare recurrence- and complication- rates for patients with IH undergoing either pure hydrocelectomy (puH) or hydrocelectomy in combination with resection of the epididymis (HRE).

Materials and Methods:

We reviewed all male patients who underwent surgical therapy for IH between 05/2003 and 02/2019 at our institution. Patient characteristics and perioperative data were collected. Furthermore complication- and recurrence- rates during follow-up were gathered and compared between different surgical techniques. A postoperative relapse was defined as a new onset of a hydrocele during follow-up.

Results

A total of 259 patients were identified. HRE was performed in 152 (58.7%) cases and 107 (41.3%) patients underwent puH. Patients in the HRE group were older (62 vs. 38 years, $p < 0.001$), were more often on platelet aggregation inhibitors (PAI) (29% vs. 8%, $p = 0.011$) and had a longer median operative time (75 vs. 60 minutes, $p < 0.001$) in comparison the puH group.

Overall complications were observed in 27 (17.8%) cases after HRE compared to 20 (18.7%) cases after puH ($p = 0.373$). Most common complications were hematoma, infection and wound dehiscence. Patients after HRE had less often Clavien-Dindo Grade 3b complications (re-interventions) compared to the puH group (7 (4.6%) vs. 12 (7%) cases, respectively, $p = 0.034$).

During a median follow-up time of 47 months, a similar amount of hydrocele recurrence was found for HRE (4 (2.6%) patients) and puH (2 (1.9%) patients).

Conclusion

Both surgery types for IH showed similar results. However, less relevant complications were seen when HRE was performed despite the fact that patients were older and were more often on PAI. Observed recurrences rates were low with less than 3% with no differences between HRE and puH. Thus, this study could not confirm that the additional epididymis resection during hydrocele treatment is associated with better long-term outcome.

P78 Hématome testiculaire spontané : une présentation de deux cas

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Introduction :

Une pathologie rare pouvant être à l'origine d'une masse testiculaire est l'hématome testiculaire spontané. Seuls quelques cas sont retrouvés dans la littérature. Nous présentons ici deux cas d'hématomes spontanés ayant une présentation clinique et radiologique très proche d'une tumeur testiculaire.

Présentation de cas :

Il s'agit de deux patients de 38 et 35 ans qui présentent des douleurs testiculaires d'apparition spontanée, sans notion de traumatisme, ainsi qu'une palpation et une échographie suspecte pour une tumeur testiculaire. Dans un cas, l'IRM, évoque le diagnostic d'hématome. L'évolution a été favorable, confirmant le diagnostic, avec une régression progressive de la taille de l'induration. Dans le deuxième cas, la clinique, l'ultrason et l'IRM étant suspects pour une lésion tumorale, le patient bénéficie d'une orchidectomie. L'examen anatomo-pathologique post-orchidectomie permet de poser le diagnostic. Dans les deux cas, un suivi doit être effectué, le diagnostic différentiel pouvant être une tumeur fugace du testicule (burned out testis tumor), pouvant potentiellement métastaser dans le rétro-péritoine.

Conclusion :

La connaissance de cette pathologie rare est importante en raison de sa présentation clinique proche de la tumeur testiculaire, afin d'éviter une intervention superflue. L'IRM peut poser le diagnostic dans certains cas, mais un suivi reste nécessaire, d'une part pour évaluer la régression de l'hématome, d'autre part pour s'assurer de ne pas avoir à faire à une tumeur fugace du testicule.

P79 Differing practice among penile cancer surgeons performing radical inguinal lymph node dissection in men with penile cancer

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INTRODUCTION:

Inguinal lymph node dissection (ILND) is an essential component in the management of penile cancer patients. Due to the rarity of the disease, high-level evidence for ILND remains scarce. The aim of this study was to investigate penile cancer surgeons' preferences for ILND.

METHODS:

An online survey was sent to penile surgeons experts including members of the European Reference Network on urogenital diseases and conditions (eUROGEN) and international experts. Data collected included surgical practice preferences and postoperative management.

RESULTS:

A total of 56 surgeons from 15 countries participated including 47 lower volume (0-20 ILND/year) and 8 higher volume (>20 ILND/year) centers. Median anticipated hospital stay is 5 (range 1-10) days. All centers reported to primarily perform open ILND, although 3 surgeons occasionally perform minimally-invasive surgery using between 2 and 5 ports. Open incisions included linear transverse in 91% (31/34), vertical lazy S in 6% (2/34) and 2cm above the inguinal ligament in 3% (1/34). Among surgeons performing linear transverse incisions, the incision is primarily performed 1cm below the groin crease (68%, 21/31) followed by 1cm above the groin crease (29%, 9/31) and within the groin crease (3%, 1/31). The different surgical templates will be presented. Nearly all surgeons (97%, 34/35) put a wound drain after the procedure with a median size of 14 French (Range 8-19) and most apply suction (89%, 31/35). Drain fluid volumes to trigger vacuum or drain removal varies between 0-100ml/24h. Post-operative antibiotics are prescribed by 71% (25/35) varying between 1 day and until drain removal. Low molecular weight heparin after discharge for a median of 28 days is prescribed by 43% (15/35).

CONCLUSIONS:

Among international penile cancer surgeons, there is variation in management preferences. These results are the foundation for a consensus conference to plan multicenter clinical trials.

P80 Limbische Enzephalitis als Erstsymptom eines burned-out-Keimzelltumors - Ein Fallbericht

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Hintergrund:

Hodentumoren fallen in der Mehrzahl der Fälle durch einen palpatorisch suspekten Lokalbefund auf. Im vorliegenden Fallbericht jedoch erfolgte die Diagnosestellung über Umwege aufgrund einer komplexen und extrem seltenen paraneoplastischen Symptomatik. Weltweit sind bisher nur wenige derartige Fälle beschrieben.

Fallbeschreibung:

Wir berichten über den Fall eines 46-jährigen Patienten welcher aufgrund von Kopfschmerzen, geistiger Verwirrung sowie Koordinations- und Gedächtnisstörungen zunächst neurologisch abgeklärt und behandelt wurde. Ein MRT des Schädels zeigte eine Enzephalitis. Sowohl eine infektiöse Ursache als auch eine Autoimmunenzephalitis konnten ausgeschlossen werden. Eine immunologische Analyse des Liquors zeigte Anti-Ma2/Ta Antikörper als Korrelat für eine limbische Enzephalitis. Bei Verdacht auf paraneoplastisches Syndrom wurde der Patient uns zum Ausschluss eines Hodentumors zugewiesen. Sonographisch stellten sich die Hoden beidseits mit echoarmen Arealen dar, die Werte für die Tumormarker AFP, hCG und LDH waren normwertig. Der Testosteronwert lag auf Kastrationsniveau. Computertomographisch konnten keine Metastasen nachgewiesen werden. Nach beidseitiger hoher inguinaler Semikastratio zeigte sich histologisch eine ausgedehnte Fibrose mit Hodenatrophie, dystrophen Kalkablagerungen und herdförmigem Nachweis einer intratubulären Keimzellneoplasie (IGCNU), welche deutlich PLAP positiv waren. Histopathologisch war der Befund somit mit einem burned-out-Keimzelltumor vereinbar. Nach Besprechung an unserem interdisziplinären Tumorboard wurde entschieden eine nächste Bildgebung mittels Computertomographie 8 Wochen postoperativ durchzuführen. Zudem wurde eine Testosteronsubstitution eingeleitet. Der weitere klinische Verlauf bleibt abzuwarten.

Schlussfolgerungen:

Burned-out-Keimzelltumoren sind extrem selten, die Diagnose gestaltet sich oft schwierig. Histologisch findet sich häufig eine Hodenatrophie mit fibrotischem Umbau des Hodengewebes sowie vereinzelt auch Mikrokalzifizierungen, der direkter Karzinomnachweis des untersuchten Gewebes gelingt oft nicht. Noch viel seltener verursachen diese Tumoren jedoch ein paraneoplastisches Syndrom mit limbischer Enzephalitis.

M1 Diagnostic yield of cystoscopy and CT-urography for urinary tract cancers in patients evaluated for asymptomatic microscopic hematuria: a systematic review and meta-analysis

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OBJECTIVE:

Asymptomatic microscopic hematuria (AMH) is a common finding leading to evaluation for urinary tract cancer (UTC). Currently there is no consensus to the extent of evaluation of these patients. The objective of this systematic review and meta-analysis was to evaluate the diagnostic yield for UTC, namely bladder cancer (BC), upper tract urothelial cancer (UTUC), and renal cancer (RC), in patients worked up for AMH by cystoscopy and CT Urography (CTU).

METHODS:

Medline, Scopus and EMBASE were systematically searched for eligible studies published between 2009 and 2019. We defined the prevalence as the proportion of patients diagnosed with UTC (BC, UTUC, and RC) following presentation with AMH. Studies were quantitatively synthesized by a random intercept logistic regression model, overall and stratified by cystoscopy and CTU utilization ($\geq 95\%$ vs. $< 95\%$ or not reported) and high-risk cohorts. The diagnostic yield for CTU and cystoscopy was calculated for each malignancy.

RESULTS: Of 5802 articles identified, 28 studies were considered eligible for meta-analysis. In total 23929 Patients with AMH were evaluated for BCA and 19519 for UTUC and RC. The pooled diagnostic yield in all patients was 2.1 % (95 % CI: 1.28 - 3.43 %) for BC, 0.02 % (95 % CI: 0.00 - 0.16 %) for UTUC and 0.2 % (95 % CI 0.15 - 0.27 %) for RC. Stratifying studies to usage of cystoscopy and/or CTU for $\geq 95\%$ of patients, the diagnostic yield was 2.85 % (95 % CI: 1.84- 4.41 %), 0.09 % (95 % CI: 0.01 - 0.75 %) and 0.1% (95 % CI: 0.04 - 0.23 %) for BC, UTUC and RC, respectively. In high risk cohorts the diagnostic yield increased to 4.69 % (95 % CI: 2.37 - 9.08 %) for BC and 0.45 % (95 % CI: 0.22 - 0.95 %) for UTUC respectively.

CONCLUSION: Based on our analysis the prevalence of UTC in patients with AMH is quite low, especially low for UTUC and RC. Considering the potential risk of ionizing radiation, adverse reaction to contrast media and costs the beneficial use of CTU evaluating AMH seems questionable at best. Even routine evaluation by cystoscopy in all patients with AMH seems to be debatable. An individual risk-stratified evaluation based on personal risk factors and with available nomograms or calculators would be very helpful but remains an open research question, yet.

M02 Comparison of Ureteroenteric Stricture Rates after Robot-Assisted Radical Cystectomy in 127 patients: Intra- versus Extracorporeal Urinary Diversion

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Introduction:

Our objective was to investigate the rates of benign ureteroenteric strictures (UES) and consecutive interventions according to the surgical approach of urinary diversion - intracorporeal (ICUD) versus extracorporeal urinary diversion (ECUD) - among patients who received robot-assisted radical cystectomy (RARC).

Methods:

We retrospectively reviewed all patients who underwent RARC at our institution since 2011. We performed ECUD until 2015. Afterwards, ICUD was our surgical approach of choice. Two robotic surgeons carried out all RARCs. The urinary diversion types were ileal conduit and orthotopic Studer neobladder. The Wallace technique was used for all ureteroenteric anastomosis. The primary outcome was the rate of UES, which was defined as hydronephrosis requiring intervention due to renal function impairment, local pain, or urinary tract infection. Inverse probability of treatment weighting (IPTW) regression analyses were applied to adjust for age, gender, BMI, Charlson comorbidity index, diversion type, and neoadjuvant chemotherapy.

Results:

Overall, 127 patients, 82 (64.6%) who underwent ICUD and 45 (35.4%) with ECUD, were included in the study. The median age was 67 (interquartile range 62-75) years. Within the ICUD and ECUD group, 23 (28%) and 14 (31%) patients received an orthotopic neobladder, respectively. During follow-up, 10 (12.2%) patients with ICUD and 7 (15.6%) with ECUD developed a UES, whereof 8 (9.8%) and 7 (15.5%) patients required primary ureteral stenting, respectively. Reimplantation surgery was necessary in 3 (4.2%) and 4 (8.9%) patients, respectively. After IPTW-adjustments, the odds of developing UESs (odds ratio [OR] 0.98, confidence interval [CI] 0.87-1.11, $p=0.8$) and ureteral stenting (OR 0.95, CI 0.84-1.07, $p=0.4$) were comparable in both treatment groups.

Conclusions:

Ureteroenteric stricture rates after RARC are comparable between the intracorporeal and extracorporeal urinary diversion approach. Furthermore, the stricture rates are congruent with previously published series. Our results suggest that the surgical technique may play an inferior role to prevent UES.

M03 Perioperative Outcomes of Robot-assisted Radical Cystectomy: A Comparison of Intracorporeal versus Extracorporeal Urinary Diversion

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Introduction:

An increasing number of centers are performing laparoscopic robot-assisted radical cystectomy (RARC) with intracorporeal urinary diversion (ICUD) replacing the extracorporeal urinary diversion (ECUD). The objective was to compare perioperative outcomes and complication rates of both approaches.

Methods:

We retrospectively reviewed all patients who underwent RARC at our institution between 2011 and 2019. Until July 2015 we performed ECUD and started with ICUD in August 2015. All RARCs were performed by two robotic surgeons. Demographic and perioperative outcome data were collected from our retrospective registry. Primary outcomes were time to first flatus, time to first bowel movement, time to full meal and the need for gastric tube. Secondary outcomes were operative time, intraoperative blood loss, hospital stay, early (< 30 d) and late (30 - 90 d) postoperative complication rates, stratified according to the Clavien-Dindo classification. Ethic approval was obtained by the local review board. We performed inverse probability of treatment weighting (IPTW) regression analyses to adjust for the effects of clinicopathologic confounders.

Results:

Overall, 127 patients with a median age of 67 (interquartile range 62 - 75) years were included. ICUD and ECUD were performed in 82 (64.6%) and 45 (35.4%) patients, respectively. Among all RARC, 37 (29.1%) patients received an orthotopic neobladder and 90 (70.8%) received an ileal conduit. After IPTW-adjustments of both treatment groups, the ICUD group was associated with decreased time to first flatus (mean - 1.1 d, $p = 0.001$), less blood loss (mean - 339.5 ml, $p < 0.001$), and shorter hospital stay (mean - 5.1 d, $p < 0.001$), but not with time to first bowel movement (mean + 0.2 d, $p = 0.6$), time to full meal (mean + 0.5 d, $p = 0.4$) and the need of gastric tube (odds ratio [OR] 1.02, $p = 0.2$). Overall, the probability of early complications (OR 1.10, $p = 0.3$) did not significantly differ between the treatment groups, while the probability of late complications (OR 0.85, $p = 0.03$) was lower in the ICUD group.

Conclusions:

RARC with ICUD was associated with reduced blood loss, shorter hospital stay and decreased risk of late postoperative complications in comparison to ECUD. Our primary hypothesis of improved postoperative bowel function after ICUD was not observed. This study is limited by its retrospective design and small sample size.

M04 The impact of treatment modality on survival in patients with clinical node positive bladder cancer

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To assess the impact of perioperative chemotherapy on survival in cN+ BCa patients and analyze it according to the pN status.

Methods:

Retrospective analysis of 639 BCa patients with cTanyN1-3M0 BCa treated with radical cystectomy (RC) and bilateral lymph node dissection (LND) with or without perioperative chemotherapy in ten tertiary referral centers from 1990 to 2017. Selected cN+ patients received induction chemotherapy (IC), whereas adjuvant chemotherapy (ACT) was delivered to selected pN+ patients. Univariable and multivariable Cox regression analyses were used to predict overall mortality (OM) after surgery, adjusting for clinic-pathological confounders. Kaplan-Meier analyses assessed OM according to treatment modality.

Results:

Overall, 356 (56%) patients were treated with surgery alone, 155 (24%) with IC followed by surgery, and 128 (20%) with ACT following surgery. Over a median follow-up of 25 months, 316 deaths were recorded. At univariable analysis, patients treated with IC and surgery had lower OM both considering cN+ (hazard ratio [HR] 0.65, 95% confidence interval [CI] 0.49-0.87, $p = 0.004$) and cN+pN- patients (HR 0.61, 95% CI 0.37-0.99, $p = 0.05$) compared to those treated with surgery alone. cN+pN+ patients treated with ACT experienced lower OM compared to those treated with IC or surgery alone at multivariable analysis (HR 0.40, 95%CI 0.22-0.74, $p = 0.003$).

Conclusion:

Patients with cTanyN+cM0 BCa benefit more in terms of OS when treated with IC followed by RC+LND compared to RC+LND alone regardless of LNMs at final histopathology examination. More data are needed to assess the role of ACT in the management of cN+ patients.

M05 Robot-assisted intracorporeal orthotopic bladder substitution after radical cystectomy: perioperative morbidity and oncological outcomes – a single institution experience

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Objective:

To report a single institution experience with totally intracorporeal neobladder urinary diversion after robot-assisted laparoscopic radical cystectomy (RARC).

Patients and methods: A total of 158 patients underwent totally intracorporeal neobladder urinary diversion after RARC between 2003 – 2016. Patient demographics, intraoperative- and pathologic data, 30-d and 90-d perioperative mortality and complications were recorded. Complications were classified according to the modified Clavien-Dindo classification. Five year overall and disease-specific survival rates were estimated by Kaplan-Meier plots.

Results:

The majority of the patients were male (84%) and had clinically T-stage ≤ 2 (87%). Mean operation time was 359 min (SD ± 98) with a median estimated blood loss of 300ml (50-2200). Most of the men (86%) received a nerve-sparing procedure and 38% of the females an organ-sparing approach. A lymph node dissection was performed in 156 (99%) cases with a median yield of 23 (7-48). Conversion to open surgery occurred in 5 patients (3%). We recorded negative margins in 156 patients (99%). Median follow-up time was 34 months (1-170) with a 30-d and 90-d mortality rate of 0%. Clavien III-IV complications occurred in 29 of 158 (18%) patients at 30-d and in 8 of 158 (5%) between 30-90d resulting into a 90-d overall high-grade complication rate of 23%. The unadjusted estimated 5y recurrence-free (RFS), cancer specific (CSS) and overall survival (OS) rates were 70%, 72%, and 71%, respectively.

Conclusion:

In our series, the complication and oncologic results were similar to open radical cystectomy series, suggest that RARC followed by totally intracorporeal neobladder urinary diversion is a safe and feasible alternative.

M06 Trimodal therapy versus radical cystectomy for T2 bladder cancer: real-world evidence from Ontario

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Introduction:

Comparative effectiveness research between trimodal therapy (TMT) and radical cystectomy (RC) for muscle-invasive bladder cancer is conflicting. Prior systematic reviews and meta-analyses in favor of RC were mainly driven by large US-based registry studies at high risk of bias. Hence, we aimed to compare the survival among patients diagnosed with T2 bladder cancer who either initiated TMT or underwent RC in a Canadian population-based cohort adjusted for a wide range of assumed confounders.

Methods:

Province-wide pathology reports (04/2004-12/2015) were linked with health administrative data to identify patients diagnosed with T2 bladder cancer. We compared 90-day mortality and cancer-specific survival (CSS) between patients who initiated TMT and patients who underwent RC by multivariable regression analysis. Effect sizes (reference: RC) were presented as adjusted odds ratios (aOR) or hazard ratios (aHR) [95% confidence interval].

Results:

We identified 1890 patients who were diagnosed with T2 bladder cancer of which 188 (9.9%) initiated TMT (median dose: 60 Gray; most common radiosensitizer: cisplatin; salvage RC rate: 9%) and 1702 (90.1%) underwent RC. Median follow-up time was 1.9 years. 90-day mortality was significantly lower in patients who initiated TMT compared to patients who underwent RC (crude rate: 2.7% versus 7%, $p=0.03$; adjusted aOR: 0.26 [0.10-0.66]). A statistically significant difference in CSS could not be observed (aHR: 0.96 [0.59-1.54]).

Conclusions:

To our knowledge, this cohort study conducted in a setting with regionalized cancer care is the first population-based study that confirms, in comparison to prior US-based registry cohorts, the similar survival outcomes between TMT and RC observed in single-center comparative studies. However, we detected a 90-day mortality rate among patients who underwent RC that was more than twice as high as the one seen among patients who initiated TMT.

M07 Oncologic long-term benefit of re-TUR in primary T1 bladder cancer: a population-based cohort study from Ontario

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Introduction:

A second transurethral resection within 2 to 6 weeks after the initial resection, a so-called re-TUR, is recommended for patients diagnosed with primary T1 bladder cancer as prior studies suggest a therapeutic, diagnostic, and prognostic benefit. Results on mortality endpoints, however, are sparse and conflicting. Hence, we aimed to provide real-world evidence by investigating the oncologic long-term benefit of re-TUR at the population level.

Methods:

Retrospective population-wide observational cohort study based on pathology reports linked to health administrative data. We identified patients who were diagnosed with primary T1 bladder cancer in the province of Ontario (01/2001-12/2015) and used billing claims to ascertain whether they received re-TUR within 2 to 10 weeks. The time-dependent effect of re-TUR on survival outcomes was modeled by Cox proportional hazards regression (unadjusted and adjusted numerous assumed patient- and surgeon-level confounders). Potential residual confounding was verified by a trace outcome (time to cataract surgery). Effect measures were presented as hazard ratios and 95%-confidence intervals.

Results:

We identified 7666 patients with non-missing covariates of which 2162 (28.7%) underwent re-TUR after a median time of 45 days (interquartile range: 35-56 days). During any time of follow-up, patients who received re-TUR were less likely to die from any causes (0.68 [0.63-0.74], $p < 0.001$) or from bladder cancer (0.65 [0.57-0.76], $p < 0.001$). After adjusting for all measured confounders, re-TUR was still associated with a lower rate of death (overall survival: 0.88 [0.82-0.95], $p=0.002$; cancers-specific survival: 0.87 [0.75-1.02], $p=0.08$). Based on the trace outcome, the suspicion for substantial residual confounding is low.

Conclusions:

This population-wide study represents one of the largest datasets of T1 tumors assembled and provides real-world evidence supporting the utilization of re-TUR in primary T1 bladder cancer.

M08 Prognostic value of second-look transurethral resection for T1 high-grade bladder cancer

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Introduction

According to current guidelines, second-look transurethral resection is recommended for T1 non-muscle invasive bladder cancer (NMIBC) within 2-6 weeks from initial transurethral resection of the bladder (TURB). Our aim was to review all patients who received TURB for T1 high-grade NMIBC at our institution.

Methods

We retrospectively reviewed all patients who underwent complete first followed by second-look TURB since 2009. Primary outcome was the rate of early recurrence / residual disease at second-look TURB. As secondary outcomes, we investigated the rates of disease recurrence, progression, and radical cystectomy during follow-up. Inclusion criteria were primary T1 high-grade bladder cancer, irrespective of concomitant carcinoma in situ (CIS), postoperative intravesical chemotherapy or immunotherapy (bacillus calmette-guérin).

Results

Overall, we included 59 patients who underwent first TURB followed by second-look TURB. The median age was 72 (interquartile range 46-95) years. Men (75%) were more affected than women (25%) with a 3:1 ratio. At the first TURB, 49 (83%) of resected specimens included detrusor muscle. At second-look TURB, 28 (47%) patients were disease-free, while 31 (53%) had early recurrence / residual disease. The second-look histopathologic results revealed no upstaging to muscle-invasive disease ($\geq T2$), nine (15%) cases with T1, 10 (17%) cases with Ta, and 12 (20%) cases with CIS only. We observed concomitant CIS in seven (22%) patients. Early recurrence at second-look occurred in 25 (80%) patients at the same location, in three (10%) at different, and in three (10%) on both location types. During a median follow-up of 30 month, overall recurrence was found in 25 (42%) and progression in eight (14%) patients, while 17 (68%) and seven (87.5%) of them had second-look recurrence, respectively. Among patients with second-look recurrence, nine (29%) needed radical cystectomy during follow-up. On the other hand, no cystectomy was necessary for patients who were disease-free at second-look.

Conclusions

Patients with second-look recurrence had increased rates of disease recurrence, progression and radical cystectomy during follow-up. Our results seem to confirm that the histopathologic outcome of second look TURB in patients with primary T1 NMIBC is of utmost importance for prognosis and should be considered for further treatment decision-making.

M09 Ergebnisse einer einarmigen Phase I/II Studie mit dem rekombinanten Bacillus Calmette Guérin (BCG) VPM1002BC bei Patienten mit high-grade Urothelkarzinomrezidiv nach BCG Induktion mit oder ohne BCG Erhaltung – SAKK 06/14

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Einleitung:

VPM1002BC ist ein genetisch modifiziertes BCG mit potentiell verbesserter Immunantwort und Verträglichkeit.

Patienten und Methoden:

Patienten mit Rezidiv eines nicht-muskel-invasiven Urothelkarzinoms (EAU Progressions Score > 7) nach adäquater BCG Induktion mit oder ohne BCG Erhaltung konnten in die Studie eingeschlossen werden. Ziel der einarmigen Studie war eine Rezidivfreiheit in der Blase 60 Wochen nach Studienregistration von $\geq 30\%$. Die Behandlung beinhaltete eine Standard Induktion von 6 Instillationen, gefolgt von 3 Erhaltungszyklen mit je 3 Instillationen über 1 Jahr. Zwischen September 2015 bis April 2018 wurden total 40 Patienten (6 aus der Phase I) in die Studie eingeschlossen. Im Falle eines Rezidivs wurde die Behandlung gestoppt.

Ergebnisse:

Die Studienpopulation bestand aus 4 Frauen und 36 Männern (medianes Alter 72 Jahre), wovon 21 (52.5%) eine Raucheranamnese hatten. Alle Patienten zeigten für den Einschluss high-grade Tumoren. Sechzig Wochen nach Registrierung betrug die Rezidivfreiheit in der Blase 49.3% [95% CI 32.1%, 64.4%]. Zur gleichen Zeit zeigten sich ein Progress im Tumorstadium, in der Tumorentdifferenzierung oder ein neues CIS in 12 (30%) Patienten (3 mit Progress zu muskel-invasivem Karzinom). Zwei Patienten starben am Urothelkarzinom (> 1 Jahr nach Therapiestart). Behandlungsassoziierte Nebenwirkungen Grad 1, 2, 3 und 4 zeigten sich in 15%, 52.5%, 5% und 0% der Patienten. Die häufigste Nebenwirkung waren Harnwegsinfekte (n=14). Zwei Patienten tolerierten nicht mehr als 4 Instillationen während der Induktion, 15 Patienten (37.5%) erhielten alle geplanten Instillationen.

Schlussfolgerungen:

Ein Jahr nach Behandlungsbeginn mit VPM1002BC zeigen fast die Hälfte der Patienten kein Rezidiv nach vorherigem BCG Versagen.

M10 Health-related Quality of Life in long-term Prostate Cancer Survivors after Nerve-Sparing and Non-Nerve-Sparing Radical Prostatectomy – Results from the multiregional PROCAS study

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Background & Aim:

Nerve-sparing (NS) surgery was developed to improve postoperative sexual and potentially urological outcomes after radical prostatectomy (RP). However, it is largely unknown how NSRP affects health-related quality of life (HRQoL) including urinary and sexual outcomes in prostate cancer (PC) survivors 5 - 10 years after diagnosis in comparison to Non-NSRP. Therefore, the objective of our study was to identify differences and similarities in general HRQoL and PC-specific symptom burden by NSRP (uni/bilateral) and Non-NSRP in long-term PC survivors.

Methods:

The study population included 382 stage pT2 - T3N0M0 PC survivors 5 - 10 years post-diagnosis, who were identified from the multiregional Prostate Cancer Survivorship in Switzerland (PROCAS) study. Briefly, in 2017 / 2018, PC survivors were identified via six population-based cancer registries based in both German- and French-speaking Switzerland. HRQoL and PC-specific symptom burden was assessed using the EORTC QLQ-C30 and EORTC QLQ-PR25 questionnaires. Differences in HRQoL outcomes between survivors treated with NSRP (uni- & bilateral) and Non-NSRP were analysed with multivariable linear regression adjusted for age, years since diagnosis, cancer stage, comorbidities at diagnosis and further therapies, if appropriate. Multiple imputation was performed to minimize the bias due to missing data.

Results:

5 - 10 years after diagnosis, PC survivors treated with NSRP and Non-NSRP reported similar symptom burden and comparable HRQoL function scores. The only significant differences were reported for sexual activity, whereas PC survivors who underwent NSRP reported statistically significant ($p = 0.031$) higher sexual activity than those on Non-NSRP. NSRP and Non-NSRP reported similar scores for urinary symptoms and all other HRQoL outcomes.

Conclusions:

NSRP and Non-NSRP were generally associated with comparable long-term HRQoL outcomes, but NSRP was linked with significantly higher sexual activity scores than Non-

NSRP. Our results support nerve-sparing techniques as an option to improve post-operative sexual but not urinary outcomes after RP in long-term PC survivors.

M11 The impact of positive surgical margins on biochemical recurrence-free survival in patients treated with robot-assisted radical prostatectomy: a single center experience

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Introduction and objectives:

Positive surgical margins (PSM) at RP have shown to increase the risk of biochemical recurrence (BCR) after RP. However, previous experiences suggested that the extent of PSM, pathological stage and pathological grade might influence the risk of BCR. Therefore, we aimed at analyzing if a 3 mm PSM cut-off might distinguish patients with an increased risk of BCR after RP.

Materials:

We retrospectively analyzed data of 1052 consecutive PCa patients treated with robot-assisted RP with or without lymph node dissection in a single referral center between November 2008 and January 2020. PSM status was defined as any tumor cell at the inked surface of the RP specimen, and was stratified according to a 3mm cut-off. In case of multifocal PSM, the cumulative longitudinal extension of PSM was considered. BCR was defined as two consecutive postoperative PSA levels of ≥ 0.2 ng/mL. Subgroups analyses were conducted by stratifying patients according to the pT stage, the pN stage and the ISUP grade, as follows: pT2-3 pN0 ISUP1-2 (Group 1), pT2-3 pN0 ISUP3 (Group 2), pT2-3 pN0 ISUP4-5 (Group 3), pT4 pN-any ISUP-any and pT-any pN+ ISUP-any (Group 4). Kaplan-Meier estimates were used to display the risk of developing biochemical recurrence after RP. Multivariable Cox regressions were used to predict the risk of BCR.

Results:

Overall, 195 patients (18.5%) had PSM at RP; of these, 186 (95%) had complete data regarding PSM extent. In total, 70 (38%) and 116 (62%) patients had a PSM extent below and above a 3mm cut-off, respectively. At a median follow-up of 5-years, the rate of BCR-free patients was 60% for negative surgical margins, 37% for PSM < 3mm and 19% for PSM \geq 3mm ($p < 0.001$). In patients with pT2-3 pN0, only \geq 3mm PSM was significantly associated with an increased risk of BCR ($p = 0.09$) in comparison with patients with negative surgical margins, irrespective of the ISUP grade. In patients with pT4 or pN+ PCa, PSM was a risk factor for developing BCR both if < 3 mm (HR 2.43, 95% CI 1.34-4.40, $p < 0.03$) and if \geq 3mm (HR 2.04, 95% CI 1.26 - 3.27, $p < 0.03$).

Conclusions:

Patients with < 3mm PSM and pT2-3 pN0 PCa have a similar risk of developing post-operative BCR in comparison with patients with negative surgical margins, regardless of the ISUP grade. In patients with pT4 or pN+ PCa, PSM is a risk factor for developing BCR, irrespective of its extent.

M12 AURORA – a 3D model guided fresh frozen section study in nerve sparing robot-assisted radical prostatectomy (NS-RARP)

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Background

Nerve-sparing procedures during radical prostatectomy have grown in significance as they reveal superior functional outcomes in terms of erectile function [1]. Data suggests the neurovascular bundle (NVB) should be removed in case of any doubt regarding residual tumor. Alternatively, intraoperative fresh frozen-section (FFS) can help guide this decision, while standard procedures of FFS don't provide a direct visual impression of the positive surgical margin (PSM) area to improve precision for a selective secondary resection (SSR) [2–7]. To improve oncologic safety while offering maximal functional outcome we intend to optimize precision of SSR by using 3D prostate models.

Methods:

62 patients in which NS-RARP was performed have been prospectively recruited since September 2018 at the University Hospital Basel and Cantonal Hospital Baseland. Image data of the preoperative pelvic MRI scan were used to create personalized virtual and printed 3D prostate models. PIRADS lesions (> grade 3) and their capsular relation were color-characterized in the model. The model was used during surgery to (i.) guide pathologist marking a positive surgical margin (PSM) and (ii.) surgeons in orientation for SSR.

Results:

52 patients had a pT2 and 10 patients a pT3 tumor. Preliminary data show that 16% (10/62) of all patients had a persistent PSM in final histology regarding 13% in pT2 and 3% in pT3 tumors. 12 patients had PSM in FFS. In 8 out of 12 patients a PSM area was marked in the 3D model involving a PIRADS lesion. Following SSR only 2 of these 12 PSM areas were not defined as tumor-free in final pathology. All other cases of incomplete resected tumors (8/62) were pT2 tumors and were missed in FFS resulting in a false negative ratio of FFS of 16%.

Conclusion

With our method conversion from PSM in FFS to R0 (no PSM) in final pathology was achieved in 83% of all patients. However, even with guidance of a personalized 3D model a relevant ratio of a false negative FFS still remains. Right now, we are working on a fully augmented reality, virtual 3D model dynamically integrated in the 3D view of the DaVinci console orientating the surgeon during SSR (Augmented Reality Robot-assisted Radical prostatectomy – AURORA).

M13 Paramètres pronostiques de récurrence biochimique post prostatectomie radicale laparoscopique robot-assistée intégrant le volume tumoral

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Contexte

Plusieurs facteurs sont associés au risque de récurrence biochimique (RB) après prostatectomie radicale robotisée (PR). Le but de cette analyse est de déterminer si, dans une cohorte de patients opérés dans un centre universitaire, le volume tumoral pourrait constituer un facteur pronostique indépendant.

Matériel et méthode

Identification depuis un registre prospectif de tous les patients opérés entre 2006 et 2015 d'une PR dans notre centre hospitalier. Exclusion des patients sans suivi postopératoire ou sans négativité du PSA. Mesure du volume tumoral basée sur un contourage des foyers tumoraux sur des tranches de sections transversales complètes de la prostate, qui est par la suite intégré dans un logiciel informatique.

Analyse de survie par un modèle de Cox univarié puis multivarié. Analyse du volume tumoral en volume relatif (Vrel) et absolu (Va), soit en variable continue ou en tertiles (< 2 mL, 2-4 mL, > 4 mL). Inclusion d'une variable d'interaction entre le volume relatif et l'ISUP dans le modèle final.

Résultats

De 562 patients éligibles, 43 patients ont été exclus. Le modèle de régression a été réalisé sur 519 patients qui avaient un âge moyen de 63 ans, dont 31% avaient un stade \geq pT3 et 30% score ISUP \geq 3. Les patients ont été suivis avec un suivi médian de 3.7 ans, avec 108 récurrences (21%). Le modèle de survie a montré une récurrence cumulative de 6%, 13%, 18%, 23%, 26% à 1, 2, 3, 4 et 5 ans en tenant compte des perdus de vue ($p < 0.01$).

Le stade tumoral, le Vrel et Va, PSA préopératoire, ganglions positifs sur le curage, réalisation d'une épargne, le score ISUP et le statut R1 étaient statistiquement significatifs en univariés et ont été inclus dans le modèle multivarié.

En multivarié, le principal facteur associé à la RB était le score ISUP avec un HR passant progressivement de 3.6 pour le grade ISUP2 à 15.0 pour le grade ISUP 5 (comparé à l'ISUP 1). Le volume tumoral relatif était statistiquement significatif en UNI ou MULTI (HR : 1.03 pour chaque pourcent supplémentaire, $p < 0.05$).

Conclusion

Le volume tumoral relatif, est significativement associé au risque de récurrence biochimique. Le grade ISUP reste le principal déterminant de récurrence biochimique, notamment dans les ISUP élevés.

M14 Can quantitative analysis of multi-parametric MRI predict failure of focal salvage HIFU therapy in men with radio-recurrent prostate cancer?

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Aim and objectives

Focal salvage HIFU is a feasible therapeutic option in patients with suitable radio-recurrent prostate cancer. However, about one-third will go on to progress within 3 years. Interpretation of mpMRI following radiation can be challenging with the gadolinium-contrast sequences reportedly most helpful. Software-based pharmacokinetic quantitative analysis of enhanced images might predict outcome following focal salvage HIFU.

Methods

A retrospective registry analysis included 150 consecutive men who underwent focal salvage HIFU (Sonablate500) (2006-2015); 89 had mpMRI available with 49 analysable for quantitative parameters. Metastatic disease was excluded by nodal assessment on the pelvic MRI, a radioisotope bone-scan and/or choline PET/FDG scan. All men had either transperineal template prostate mapping biopsy or targeted and systematic TRUS-biopsy. mpMRI included T2-weighted, diffusion-weighted and dynamic contrast-enhancement. Pre-HIFU quantitative mpMRI data was obtained using Horos DICOM Viewer v3.3.5 for general MRI parameters and IB DCE v2.0 plug-in. Progression-free survival (PFS) was defined by biochemical failure and/or positive localized or distant imaging results and/or positive biopsy and/or systemic therapy and/or metastases/prostate cancer-specific death. Potential predictors of PFS were analysed by univariable and multivariable logistic regression.

Results

Median age at focal salvage HIFU was 71 years (IQR 65 – 74.5) and median PSA pre-focal salvage treatment was 5.8ng/ml (3.8 - 8). Median follow-up was 35 months (23 - 47) and median time to failure was 15 months (7.8 – 24.3). D-Amico Low, intermediate and high-risk disease was present in 1% (1/89), 40% (36/89) and 43% (38/89) prior to focal salvage HIFU (16% missing data). 56% (50/89) failed by the composite outcome. At univariate analysis, PSA and prostate volume at time of radiotherapy failure, V_e (median) value were predictors for failure (V_e represents extracellular fraction of the whole tissue volume). In the multivariate analysis, only V_e (median) value remained as an independent predictor.

Conclusions

Pharmacokinetic quantitative parameters of mpMRI DCE sequences seem to independently predict failure following focal salvage HIFU for radiorecurrent prostate cancer. This likely relates to the tumour microenvironment producing heat-sinks. Further validation and work to investigate mechanisms to reduce heat-sink are required.

M15 Transperineal vs transrectal micro-US MR targeted biopsy

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Aim and objectives

Micro-ultrasound (micro-US) is a high-resolution US that allows real-time targeted prostate biopsies and may improve the detection rate of MR targeted biopsy. In contrast to the transrectal (TRB) approach, the transperineal (TPB) approach is being increasingly applied to diminish infectious complications. Furthermore, it may increase the diagnostic yield. We aimed to analyze cancer detection rate in patients who underwent prostate biopsy using micro-US and to evaluate the impact of the sampling route.

Methods

Consecutive patients undergoing micro-US biopsy from May 2018 until March 2020. Men with previous local or systemic treatment were excluded. All prostate biopsies were performed using the ExactVu system (Exact Imaging™, Canada). Random and MR targeted biopsies were performed in case of MR visible lesions. Clinically significant disease (csPCa) was described as Gleason pattern ≥ 4 and/or total cancer core length ≥ 10 mm. Prostate cancer detection rate and concordance between random and target biopsies were assessed, as the difference of cancer detection rate according to the sampling route (TRB vs. TPB). Statistical significance was set at $p < 0.05$.

Results

Of 322 procedures, 56 (17%) were performed through a TRB and 266 (83%) through a TPB approach. The two groups were similar regarding age (67 vs. 66 years), PSA (6.7 vs. 7.9 ng/ml), prostate volume (40 vs. 42 ml), clinical stage (negative DRE 79% vs. 74%) and indication to biopsy. TRB group had fewer MRI lesions scored PIRADS 3-5 (57% vs. 86%; $p < 0.01$) and almost no anterior lesions (6% vs. 49%; $p < 0.01$). More biopsy cores were taken with the TPB approach in the random and in the targeted samples. TPB had higher cancer detection rate in the targeted approach ($p = 0.01$), but not in the random sampling ($p = 0.98$). TPB approach presented higher detection of csPCa as well as lower detection rate of insignificant disease than TRB group (63% vs. 36%, $p = 0.01$; 8% vs 18%, $p = 0.04$). In the overall population, micro-US detected non MR visible csPCa and insignificant disease in 14 (4%) and 12 (4%) men, respectively.

Conclusions

This study suggests that micro-US has an excellent cancer detection rate with additional added value to MR fusion biopsy. In our experience, performing biopsy through the perineum provides enhanced detection of csPCa and at the same time decreased detection of clinically insignificant disease.

M16 Analysis of tumor foci in HIFU-eligible patients undergoing radical prostatectomy

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Aim

The aim of this study was to characterize tumor foci in patients that were eligible for focal therapy for prostate cancer but ultimately underwent radical prostatectomy.

Patients and methods

Identification of patients eligible for focal therapy from a prospectively held radical prostatectomy database within a certified cancer center. Patients underwent targeted and systematic biopsies after a previous mpMRI (median no. of cylinders: 12). MRIs were read by dedicated uro-radiologists. Inclusion criteria were: PSA < 15 ng/ml, ISUP grade 1-3, tumor stage cT1-T2b cN0 cM0 on DRE and MRI, unilateral disease not involving the apex. Tumor locations were categorized as apical, mid and basal left or right. Concordance between biopsy and MRI localization was verified. In order to avoid overestimating residual cancer after therapy, we hypothesized the use of hemiablation protocols.

Patients were operated between 2013 and 2020. Two dedicated uro-pathologists performed histologic analysis with whole mount sections followed by computer-based, volumetric analysis of the prostate and tumor foci. Significant disease was defined according to Stamey.

Results

Of 486 screened patients, 54 were eligible for HIFU. Median age was 64, median PSA 7 ng/ml. Thirty-six patients (67%) had cT1 disease, 14 (26%) cT2a and 4 (7%) cT2b. ISUP grades were 1 on 18 biopsy sets (33%), 2 in 28 (52%) and 3 in 8 (15%).

Side concordance between MRI and biopsies was found in 29 of 54 patients (54%). Of these, contralateral disease (initially neither detected on MRI or biopsies) was found in 23 (79%). It was significant in 15 (52%). Capsular penetration was seen in six (21%).

Ten patients (19%) had neither significant contralateral disease, nor capsular penetration. Tumor involvement of the apex was found in five of them. At least in two, this (potentially undertreated) apical disease was significant.

Generally, in the 54 radical prostatectomy specimens, capsular penetration was seen in 12 (22%): 8 with pT3a (15%) and 4 stage pT3b (7%). ISUP grade 4 was found in 5 (9%) patients, grade 5 in one (2%).

Interestingly, results did not significantly change with more restrictive HIFU inclusion criteria (PSA ng/ml < 10 ug/l; ISUP 1-2).

Conclusion

In this cohort considering hemiablation, approx. half of the patients would have had significant residual tumors. These results underline the need for precise upfront staging, potentially by saturation biopsies, and close follow-up after treatment.

M17 Implementation of ProBio in Switzerland: An outcome-adaptive, multi-arm, open-label, multiple assignment randomised controlled biomarker-driven trial in patients with metastatic castration-resistant prostate cancer

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Background:

Despite multiple retrospective studies have demonstrated the clinical validity of molecularly-guided therapy selection in metastatic castrate-resistant prostate cancer (mCRPC), none have validated the actual clinical utility in the context of a randomised controlled trial. We hypothesise that treatment decisions based on plasma-derived cell-free DNA (cfDNA) profiling will increase progression-free survival, which would result in prolonged overall survival and improved quality-of-life.

Methods:

The Prostate Biomarker (ProBio) trial is a adaptive, multi-arm, open-label, multiple assignment randomized controlled biomarker driven phase 3 trial in men with mCRPC recently initiated in Sweden. Men are randomized to receive either standard of care or an experimental treatment with abiraterone, enzalutamide, olaparib, docetaxel, cabazitaxel, or carboplatin based on molecular biomarker signatures, as inferred from our liquid biopsy profiling. Therefor a prostate-specific 1.48 Mb biomarker panel was designed and validated, which is capable of detecting 1)mutations in 78 genes, 2)genomic structural rearrangements in 11 prostate cancer-associated genes, 3)genome-wide copy number alterations, 4)63 microsatellites to infer microsatellite instability, 4)tumour mutational burden and 5)estimate the circulating tumour DNA (ctDNA) fraction. The initial pre-defined biomarker signatures are defined as mutations in certain genes/pathways identified in the scientific literature as potentially important in prostate cancer treatment response encompassing the androgen receptor (AR), TP53, DNA-repair deficiency (DRD) and the TMRSS2-ERG fusion. The statistical design of ProBio is novel, since the randomization probabilities for a given experimental systemic therapy are subjective to change as the trial evolves and learns from prior experience. A local implementation of the diagnostic platform in Switzerland was initiated in 2020.

Results:

Applications for approval by ethical commissions and Swissmedic are ongoing. DNA extraction from blood samples and next generation sequencing have been introduced locally at the University Hospital Zurich. Bioinformatics including a software platform for curation of the sequencing data in a timely manner (7-10 days) are being implemented.

Conclusion: The technical platform of ctDNA profiling for the ProBio trial is being established in Switzerland. National centers can start in Q1/2021 with inclusion of men with mCRPC into ProBioCH.

M18 Extraperitoneal-extravesikale roboterassistierte Adenomenukleation mit intraprostatischer vesiko-urethraler Anastomose (EE-RASP): eine neue Operationstechnik bei grosser BPH

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Hintergrund und Ziele

Die roboterassistierte Adenomenukleation wurde erstmalig durch H. John am AUA 2007 als Videobeitrag vorgestellt (1). Über die Zeit wurden verschiedene transperitoneale (2) und retroperitoneale (3) sowie transvesikale wie auch extravesikale Techniken entwickelt. Die extraperitoneal-extravesikal roboterassistierte Adenomenukleation (EE-RASP) mit intraprostatischer vesiko-urethraler Anastomose ist an unserer Klinik der Standard bei Adenomen > 80 ml.

Material und Methoden

Der standardisierte extraperitoneale Zugang erfolgt mittels Ballondilatation und Einbringen der Instrumente des 4-Arm- Robotersystems unter digitaler und visueller Kontrolle. Die prostatistische Harnröhre am Blasenhal wird freipräpariert und abgesetzt. Nach stumpfer Enukleation erfolgt die urethrale Rekonstruktion zwischen Blasenhal und intraprostatischem Harnröhrenstumpf mittels fortlaufend zirkulärer Anastomose in Van Velthoven- Technik. Damit wird die Prostataloge vollständig ausgeschaltet. Die ventrale Prostatakapsel wird an die Blasenvorderwand adaptiert. Abschliessend erfolgt die Einlage eines suprapubischen sowie transurethralen Dauerkatheters.

Resultate

Bei 18 Patienten mit einem medianen Alter von 74 Jahren und einer Prostatagrösse von 127ml wurde eine EE-RASP durchgeführt. Die Operationsdauer betrug median 172 min mit einem Blutverlust von 200 ml. Der mediane präoperative Restharn resp. max. Uroflowmetrie belief sich auf 130 ml bzw. 5.6 ml/sec im Vergleich zu postoperativ mit 0 ml bzw. 14.9 ml/sec. Die Hospitalisationsdauer war 3 Tage, der transurethrale Katheter wurde am 1. postoperativen Tag entfernt, der suprapubische Katheter nach dichter Zystographie. Ein Patient hatte postoperativ initial eine undichte vesico-urethrale Anastomose. Drei Patienten zeigten postoperativ einen Harnwegsinfekt. Blutungen aus der Prostataloge kamen nicht vor. Zwei Monate nach Operation lag die mediane Anzahl an benötigten Einlagen bei null.

Schlussfolgerung

Die extraperitoneal-extravesikal roboterassistierte Adenomenukleation (EE-RASP) mit intraprostatischer vesiko-urethraler Anastomose ist eine neue minimal-invasive Technik zur Behandlung grosser Prostataadenome mit geringem intraoperativen Blutverlust und guten funktionellen Resultaten. Dank dem vollständigen Ausschalten der prostatistischen Harnröhre entfallen Prostatalogen- und Harnröhrenkomplikationen, die bei offenen oder endoskopischen Operationstechniken bestehen.