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CLINICAL STUDY

Urinary tract infection in the context of mini-invasive procedures after kidney transplantation

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ABSTRACT

INTRODUCTION: The use of antibiotic prophylaxis in invasive procedures is generally accepted and highly recommended. The question is the need to apply antibiotic prophylaxis even in the case of mini-invasive procedures in the post-transplantation period.

The aim of the study was to determine the occurrence of infectious complications during mini-invasive procedures (pig-tail extraction, protocol biopsy) without the use of antibiotic (ATB) prophylaxis. The secondary aim was to identify risk factors for a positive urine culture finding at the time of mini-invasive procedures.

MATERIAL: This is a prospective monocentric study in which patients after kidney transplantation at Transplantation centrum in Martin were included (n = 68). We investigated the incidence of positive urine findings at the time of pig-tail extraction (6 weeks after transplantation) and at the time of protocol biopsy (3 months after transplantation) with comparison within the group with and without ATB prophylaxis.

RESULTS: Patients in group without ATB prophylaxis had a significantly higher tacrolimus value at the time of pig-tail extraction (p = 0.0274) and a significantly higher dose of mycophenolic acid at the time of protocol biopsy (p = 0.0429). We did not confirm significant difference in occurrence of positive urine findings at the time of pig-tail extraction or at the time of protocol biopsy. We completed a univariate logistic regression in order to identify a potential risk predictor for positive urine findings at the time of pig-tail extraction and protocol biopsy. None of the monitored parameters, including ATB prophylaxis, was confirmed as risk or protective factor.

CONCLUSION: The use of antibiotic prophylaxis during mini-invasive procedures (pig-tail extraction, protocol biopsy) in the posttransplantation period had no effect on positive culture findings at our department. Based on our analysis, we therefore do not use antibiotic prophylaxis in the case of these procedures at our centre *(Tab. 3, Fig. 6, Ref. 23)*. Text in PDF *www.elis.sk*

KEY WORDS: antibiotic prophylaxis, pig-tail extraction, protocol biopsy, kidney transplantation.

Abbreviations: ATB – antibiotic, ATG – antithymocyte globulin, BK – BK virus, CFU – colony-forming units, CMV – cytomegalovirus, DGF – delay graft function, *E. coli* – *Escherichia coli*, ECD – expanded criteria donor, KHA-CARI – The Kidney Health Australia-Caring for Australasians with Renal Impairment, KT – kidney transplantation, MPA – mycophenolic acid, PJP – *Pneumocystis jiroveci* pneumonia, SCD – standard criteria donor, SMZ/TPM - sulfamethoxazole/trimethoprim, TAC – tacrolimus, UTI – urinary tract infection, WHO – World Health Organization, Y – year

Introduction

Urinary tract infection (UTI) is the most common complication in the early post-transplant period. Its prevalence is reported in the range 20–80 % (1). The occurrence of IMT represents a global socio-economic burden. Although the rate of this burden is relatively stable, the mortality rate has increased by 0.55% over the past decades, resulting in a 2.4-fold higher mortality rate for IMT in 2019 compared to 1990 (2). The main risk factors for the development of UTI include: gender, age at the time of transplantation, diabetes mellitus, previous UTI, abnormalities of uropoetic tract, delay graft function (DGF), triple immunosuppressive therapy, ureteral stent insertion and postoperative vesicoureteral reflux (1, 2, 3, 4).

Pig-tail as a type of ureteral stent is applied at the time of kidney transplantation to establish urinary tract continuity and minimalize surgical complication in the post-transplant period (stenosis, obstruction of vesicoureteral orifice, leakage of urine into the abdominal cavity). Despite the significant benefits of the stent, its presence is a risk factor for bacteremia, graft pyelonephritis with a possible progression to acute graft rejection and subsequent impaired graft function. Because of these reasons we performed the extraction of stent within 6 weeks after transplantation. Antibiotic (ATB) prophylaxis in perioperative period is generally accepted as the standard of therapy. The avalaible literature does not provide enough information about the need for short-term ATB profylaxis

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at the time of pig-tail extraction and also the available procedures of other centers are not uniform (3, 5).

Protocol biopsy as a second mini-invasive procedure, is usually performed in the 3rd month after transplantation. It represents the basic diagnostic pillar of subclinical rejection caused by: cellular or antibody-inducted rejection, recurrent or de novo glomerulopathy, BK-virus (BKV)-asossiated nephropaty. Early detection and treatment of subclinical rejection improves the long-term survival of the graft and thus the patient. The most serious complication of a protocol biopsy is hemorrhage, therefore the available literature focuses mainly on the prevention and treatment of this complication. The development of infection assosiated with a protocol biopsy is extremely rare. Although it is a mini-invasive procedure, it involves a violation of the continuity of the skin cover, and based on the recommendations of The World Health Organization (WHO), ATB prophylaxis should be administered within 120 minutes before the skin incision. KHA-CARI (The Kidney Health Australia-Caring for Australasians with Renal Impairment) guidelines for renal biopsy or other available literature do not state or exclude the need for ATB prophylaxis at the time of performing protocol biopsy (6, 7, 8).

The aim of the presented study is to determine the occurrence of infectious complications in the context of mini-invasive procedures (pig-tail extraction, protocol biopsy) without using antibiotic prophylaxis. Another goal is to identify the risk factors for positive urine culture finding at the time of mini-invasive procedures.

Tab. 1. Basic characteristics of kidney transplant recipients.

	without ATB prophylaxis n=35	ATB prophylaxis n=33	p
gender – men (%)	65.7 (n=23)	69.7 (n=23)	0.7265
age at the time of KT (Y)	44.9 ± 13.7	48.3 ± 15	0.3322
history of diabetes mellitus (%)	28.6 (n=10)	24.2 (n=8)	0.6833
dialysis duration (M)	29.2 ± 23.7	33.3 ± 22.9	0.4712
ECD donor (%)	14.3 (n=5)	36.4 (n=12)	0.0369
living donor (%)	5.7 (n=2)	3 (n=1)	0.5898
ATG (3,5 mg cumulative) (%)	42.9 (n=15)	51.5 (n=17)	0.4809
ATG (6 mg cumulative) (%)	8.5 (n=3)	6.1 (n=2)	0.7065
DGF (%)	5.7 (n=2)	12.1 (n=4)	0.3555
TAC value at the time of pig-tail extraction (ng/ml)	14.5 ± 4.9	12.2 ± 3.3	0.0274
dose of MPA at the time of pig-tail extraction (mg/day)	1028 ± 177	970 ± 368	0.4063
dose of Prednisone at the time of pig-tail extraction(mg/day)	10.4 ± 1.4	10.5 ± 1.5	0.7770
positive urine culture finding at the time of pig-tail extraction (%)	28.6 (n=10)	12.1 (n=4)	0.0951
symptomatic course of infection at the time of pig-tail extraction (%)	2.9 (n=1)	0	0.3279
TAC value at the time of protocol biopsy (ng/ml)	10.6 ± 4.6	8.8 ± 2.5	0.0510
dose of MPA at the time of protocol biopsy (mg/day)	905 ± 313	735 ± 364	0.0429
dose of Prednisone at the time of protocol biopsy (mg/day)	9.9 ± 1.2	10.3 ± 1	0.1414
positive urine culture finding at the time of protocol biopsy (%)	22.9 (n=8)	18.2 (n=6)	0.6376
symptomatic course of infection at the time of protocol biopsy (%)	2.9 (n=1)	0	0.3276

ECD – expanded donor criteria; ATG – antithymocyte globulin; DGF – delayed graft function; TAC - tacrolimus; MPA – mycophenolic acid, KT – kidney transplantation; M – month; Y – year

Material and methods

It is a monocentric prospective analysis, which included kidney transplant recipients transplanted from 01.01.2019 to 31.12.2019 and from 01.01.2021 to 31.12.2022 at the Transplant Centre in Martin.

Inclusion criteria:
- patient age > 18 years;
- primary/secondary/tertiary kidney transplantation;
- kidney transplantation from a living donor;
- kidney transplantation from deceased donor;
- implementation of pig-tail extraction;
- implementation of a protocol biopsy;
- provision of urine for examination at the time of mini-invasive procedures;
- patient cooperation;
- signed informed consent.

Exclusion criteria:
- patient age < 18 years;
- impossibility of performing pig-tail extraction (eg. urinating pig-tail);
- impossibility of performing protocol biopsy;
- non-cooperation of the patient;
- patient's disagreement with the examination and inclusion in the study.

Patients were divided into two groups based on the application of ATB prophylaxis during the implementation of mini-invasive procedures: pig-tail extraction, protocol biopsy.

Prophylactic ATB therapy was administered to all patient transplanted in 2019. Patients transplanted in 2021 and 2022 did not have ATB prophylaxis at the time of pig-tail extraction and protocol biopsy.

Based on the immunological risk, induction immunosuppressive therapy was applied to the recipients: basiliximab and antithymocyte globulin (ATG) in a cumulative dose of 3.5 mg/kg or

6 mg/kg. Maintenance triple immunosuppressive therapy consisted of tacrolimus (TAC), mycophenolic acid (MPA) and an oral formulation of corticoids (Prednisone). Antibiotic prophylaxis in post-transplant period included administration of sulfamethoxazole/trimethoprim (SMZ/TPM) as prevention of *Pneumocystis jiroveci* pneumonia (PTJ) for 6 months. Valganciclovir was administered for 3 months to prevent the development of cytomegalovirus (CMV) infection in CMV immunoglobulin G (IgG)-negative patients, who received a graft from a CMV-positive donor or for all recipients, regardless of pre-transplant CMV status, who received ATG induction. Fluconazole was given as prophylaxis against mycotic infection up to 3 months after transplantation.

We found the following parameters for all recipients: gender, age at the time of transplantation (years), primary diagnosis of renal failure, medical history of diabetes mellitus, dialysis duration (months), type of donor – living donor, stardard criteria donor (SCD), expanded criteria donor (ECD), type of induction and presence of DGF.

At the time of pig-tail extraction (6 weeks after transplantation) and providing the protocol fine-needle biopsy of the graft (3 months after transplantation) we checked TAC value in patients of both groups and recorded the daily dose of MPA and Prednisone. The patient's urine was also examined for culture, with subsequent quantitative recording of specific pathogens in the case of positive urine finding. At the time of the mentioned mini-invasive procedures, the patient's medical history was taken, focusing on urinary infection symptoms: burning, cutting during urination, frequency of urination, temperature (> 38 °C).

Expanded criteria donor was a donor older than 60 years or aged 50 – 59 years with at least two of the following criteria: serum creatinine level > 133 μmol/l, a history of arterial hypertension, or the cause of the death was stroke.

Delayed graft function was definied as the need of dialysis 7 days after transplantation.

A positive urine finding was defined as the presence of $\geq 10^4$ colony-forming units (CFU)/ml of urine.

In the group with ATB prophylaxis oral cephalosporin ATB (cefuroxime-axetil) was administered at a dose of 500 mg every 12 hours with application 2 days before the mini-invasive procedure, on the day of the procedure and the day after the procedure. In case of allergy to penicillin ATB, we applied fluoroquinilone ATB (ciprofloxacin) due to a possible cross-reaction.

Statistical methods

We used a certified statistical program, MedCalc version 13.1.2. (MedCalc Software VAT registration number BE 0809 344,640, Member of International Association of Statistical Computing, Ostend, Belgium). Categorical variables were presented as counts and weighted percentages. Comparisons of continuous variables between groups were carried out using parametric (t-test) or non-parametric (Mann-Whitney) tests; associations between categorical variables were analyzed using the χ^2 test and Fisher's exact test, as appropriate. Univariate logistic regression was used to assess the monitored parameters as predictors of positive urine findings at the time of pig-tail extraction and protocol biopsy. A p-value < 0.05 was considered to be statistically significant.

Ethical approval

All procedures involving human participants have been approved according to the ethical standards of ethical commitee of University hospital Martin and Jessenius Faculty of Medicine, including the 1964 Helsinki Declaration and its later amendments of comparable ethical standards. All signed informed consents are archived for at least 20 years after research completion and are available upon request. The clinical and research activities being reported are consistent with the Principles of the Declaration of Istanbul as outlined in the Declaration of Istanbul on Organ Trafficking and Transplant Tourism.

Results

A total of 68 patients (men: n = 46; 67.6 %) after kidney transplantation were included in the study. Patients were divided based on the use of ATB prophylaxis into 2 groups: without ATB prophylaxis (n = 35) and with ATB prophylaxis (n = 33). Table 1 shows the basic characteristics of both groups of patients and monitored parameters.

Patients in the group without ATB prophylaxis were significantly less often transplanted from an ECD, had a significantly higher TAC value at the time of pig-tail extraction. We also confirmed a significantly higher MPA dose in this group of patients at the time of protocol biopsy (Tab. 1).

Figures 1 and 2 show distribution of the cohort according to the underlying diagnosis of renal failure. Figures 3 – 6 show the most common pathogens in urine: *Escherichia coli (E. coli), Enterococcus faecalis, Pseudomonas aeruginosa* and *Klebsiella pneumoniae.*

With the help of univariate analysis, we further monitored the occurrence of potential predictors for a positive urine culture finding at the time of mini-invasive procedures. We did not identify any significant predictor for a positive urine finding in the patients at the time of pig-tail extraction and at the time of protocol biopsy (Tabs 2 and 3).

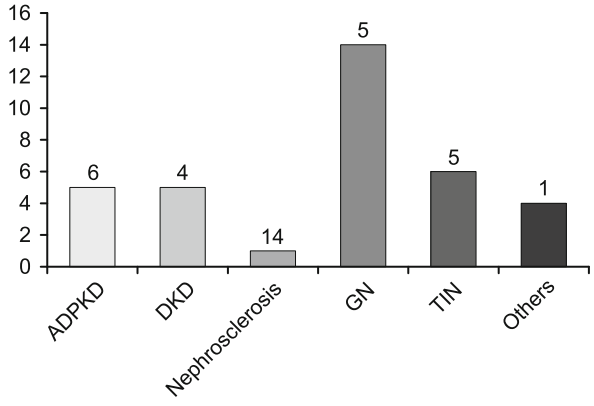

Fig. 1. Distribution of the non-ATB patients by primary diagnosis of kidney failure.

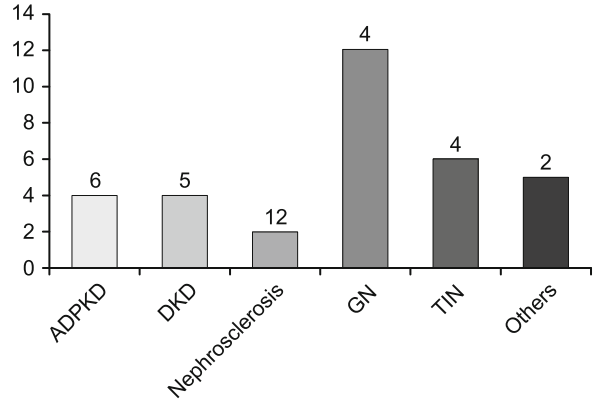

Fig. 2. Distribution of the ATB patients by primary diagnosis of kidney failure.

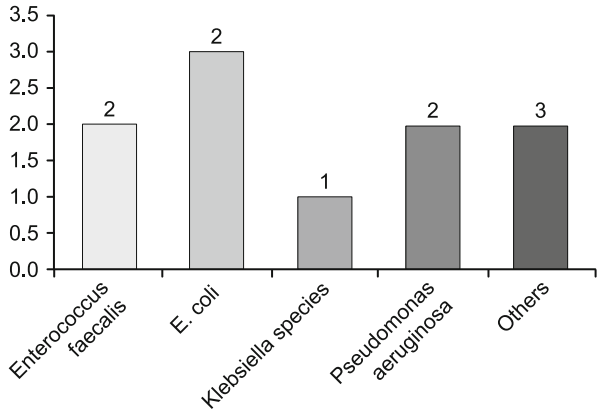

Fig. 3. Bacteria isolated from positive urine cultures at the time of pig-tail extraction in non-ATB patients (n = 10).

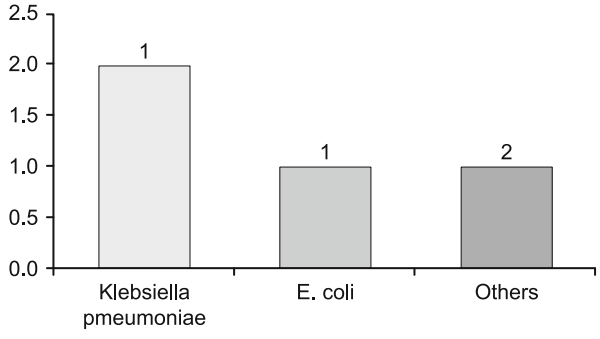

Fig. 4. Bacteria isolated from positive urine cultures at the time of pig-tail extraction in ATB patients (n = 4)

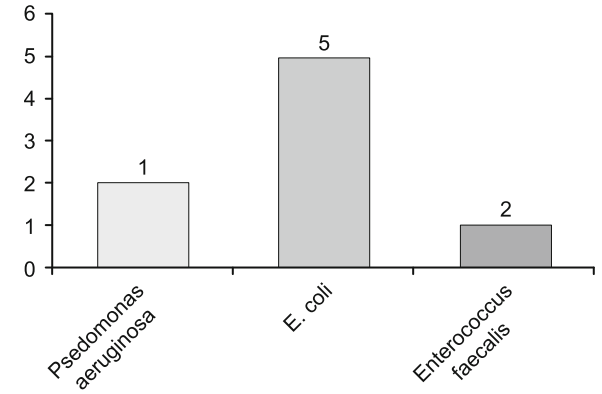

Fig. 5. Bacteria isolated from positive urine cultures at the time of protocol biopsy in ATB patients (n = 8).

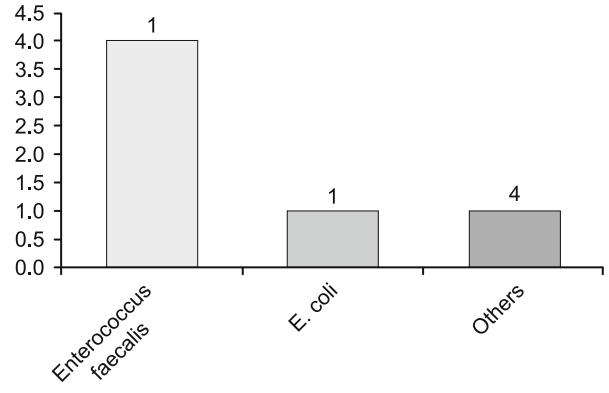

Fig. 6. Bacteria isolated from positive urine cultures at the time of protocol biopsy in non-ATB patients (n = 6).

Discussion

In our analysis, we did not confirm the occurrence of a risk factor for a positive urine finding, or urinary tract infection at the time of mini-invasive procedures (pig-tail extraction, protocol biopsy) after kidney transplantation.

In many studies, a finding of $\geq 10^5$ CFU/ml of urine was definied as a positive urine finding (3, 9, 10). According to the guidelines published by the Infectious Diseases Society of America (IDSA) asymptomatic bacteriuria is defined as the presence of at least one type of bacterial growth in urine with a bacterial count $\geq 10^5$ CFU/ml irrespective of whether pyuria is present or not and if there are no symptoms or signs attributable to UTI (11). A study by Lee et al considered the presence of $\geq 10^4$ CFU/ml as a positive urine finding, which agrees with the criteria of our analysis (5).

Risk factors for the development of urinary tract infection in the post-transplant period vary from study to study, but the available literature does not discuss UTI in the context of mini-invasive post-transplant procedures, with the exception of a study by Lee et al from 2019. Many studies identified as a risk factors for the development UTI in the post-transplant period the following: age, gender, diabetes mellitus, urinary tract abnormalities, history of UTI, inserted urinary catheter and ureteral stent (1, 10, 13). The study by Krolicky et al from 2022 identified anatomy of the transplanted kidney as a risk factor: short ureter, lacking gravity barrier for urinary reflux, and insufficient anti-reflux properties of vesico-

Tab. 2. Logistic regression – univariate analysis.

End point: positive urine culture finding at the time of pig-tail extraction	Odd ratio	95%CI	p
gender – men	0.3846	0.1153–1.2835	0.1202
age at the time of KT (Y)	0.9905	0.9504–1.0324	0.6525
history of diabetes mellitus	1.1429	0.3085–4.2338	0.8416
primary diagnosis: ADPKD	3.9200	0.8921–7.2255	0.0705
primary diagnosis: DKD	0.4423	0.0506–3.8666	0.4609
primary diagnosis: nephrosclerosis	2.0000	0.1681–3.7930	0.5833
primary diagnosis: glomerulonephritis	1.0909	0.3320–3.5845	0.8860
primary diagnosis: tubulointerstitial nephritis	0.9583	0.1796–5.1148	0.9603
primary diagnosis: others	0.3060	0.1676–1.4557	0.9980
dialysis duration (M)	0.9759	0.9371–1.0163	0.2378
ECD donor	0.4333	0.0865–2.1702	0.3090
living donor	8.8333	3.9077–10.5579	0.0852
ATG (3.5 mg cumulative)	0.3714	0.1036–1.3313	0.1283
ATG (6 mg cumulative)	0.9615	0.0989–3.9510	0.9730
DGF	0.7538	0.0809–1.7027	0.8041
TAC value at the time of pig-tail extraction (ng/ml)	1.0946	0.9615–1.2462	0.1718
dose of MPA at the time of pig-tail extraction (mg/day)	1.0000	0.9980–1.0021	0.9662
dose of Prednisone at the time of pig-tail extraction(mg/day)	0.9451	0.6047–1.4769	0.8041
ATB profylaxis	0.3448	0.0962–1.2365	0.1021

ADPKD – autosomal dominant polycystic kidney disease; DKD – diabetic kidney disease; ECD – expanded donor criteria; ATG – antithymocyte globulin; DGF – delayed graft function; TAC - tacrolimus; MPA – mycophenolic acid; KT – kidney transplantation; M – month; Y – year; ATB – antibiotic

Tab. 3. Logistic regression – univariate analysis.

End point: positive urine culture finding at the time of protocol biopsy	Odd ratio	95%CI	p
gender – men	0.8000	0.2311–2.7694	0.7247
age at the time of KT (Y)	0.9860	0.9452–1.0286	0.5146
history of diabetes mellitus	0.7679	0.1441–4.0914	0.7570
primary diagnosis: ADPKD	2.0909	0.4509–6.9961	0.3460
primary diagnosis: DKD	0.5870	0.1030–1.1704	0.9974
primary diagnosis: nephrosclerosis	0.5400	0.1884–1.1119	0.9981
primary diagnosis: glomerulonephritis	0.1667	0.0339–0.8194	0.2074
primary diagnosis: tubulointerstitial nephritis	0.4231	0.0484–3.7018	0.4370
primary diagnosis: others	3.7600	0.8547–6.5410	0.0797
dialysis duration (M)	0.9977	0.9743–1.0215	0.8455
ECD donor	1.8519	0.5204–6.5901	0.3414
living donor	0.8111	0.1950–1.5400	0.9981
ATG (3.5 mg cumulative)	2.4545	0.7219–8.3462	0.1504
ATG (6 mg cumulative)	0.9231	0.0949–8.9832	0.9450
DGF	0.7231	0.0775–6.7460	0.7760
TAC value at the time of protocol biopsy (ng/ml)	0.9057	0.7354–1.1155	0.3513
dose of MPA at the time of protocol biopsy (mg/day)	0.9057	0.7354–1.1155	0.3076
dose of Prednisone at the time of protocol biopsy (mg/day)	1.2503	0.7710–2.0274	0.3651
ATB profylaxis	0.6944	0.2112–2.2830	0.5482

ADPKD – autosomal dominant polycystic kidney disease; DKD – diabetic kidney disease; ECD – expanded donor criteria; ATG – antithymocyte globulin; DGF – delayed graft function; TAC - tacrolimus; MPA – mycophenolic acid; KT –kidney transplantation; M – month; Y – year; ATB – antibiotic

urethral anastomosis (14). In the context of gender, the female gender dominanted due to anatomical proportions, however, in the study of Velioglu et al from 2021, the incidence of UTI was more frequent in men (52 %). The results of the aforementioned study identified the following as significant risk factors: age, dialysis duration, duration of urinary catheter insertion, urological complications after transplantation (1). Pregnancy as a risk factor due to changes in the anatomical proportions of the abdomen and the immunosuppressed state of the organism was also identified as a risk factor (15). The study by Ma et al confirmed gender (women) and DGF as a risk factor for the development of UTI (4).

In the first 6 months after kidney transplantation, infections were usually related to postoperative complications, manipulation of the urinary tract or viral reactivation in the study of Protus et al from 2022 (16). Immunosuppressive therapy was not confirmed as a risk factor in any of the studies (1, 4). The underlying disease as a risk factor for a positive urine finding at the time of pig-tail extraction was not confirmed either in our analysis or in the study of Lee et al (4). An interesting result came from the study by Koga et al from 2022, where the occurrence of IMT may be related to the length and diameter of the kidney ureter from a living donor (17).

In our group of patients without ATB prophylaxis, *E. coli* (30 %) was the most frequently isolated pathogen from a positive urine finding at the time of pig-tail extraction. Many studies have shown the same result, as well as the study by Lee et al carried out with 221 patients without ATB prophylaxis – *E. coli* (40 %) (5, 18, 19). In the aforementioned study, *Coagulase-negative Staphylococci* species (45 %) dominated in patients with prophylactic administration of ATB, which did not coincide with the result of our analysis, where other unspecified species of bacteria (50 %) were detected in patients with ATB prophylaxis (5).

The result of our study did not show the prophylactic administration of ATB at the time of mini-invasive procedures (pig-tail extraction, protocol biopsy) as a significant risk, or protective factor for a positive urine finding. A study by Lee et al from 2019, which monitored risk factors at the time of pig-tail extraction, detected the same result, however, the applied SMZ/TMP as PJP prophylaxis was identified as a significant risk factor for the development of UTI (5).

Infectious complications associated with protocol biopsy are rare in today's era of aseptic approach. However, in the process of skin incision and insertion of the bioptic needle, there is a violation of the continuity of the skin, which represents an entry gate for pathogens, therefore one must be careful and detect signs of

the development of infection at an early stage and thus prevent the graft and the patient from being endangered. The advantage of the protocol biopsy compared to the biopsy of the native kidney is the surface placement of the graft, which eliminates the passage through several layers of tissue. However, a significant risk is represented by the increasingly common obesity often associated with type 2 diabetes mellitus (20, 21). The clinical study by Paudel et al shows that in comparison to their nondiabetic counterparts, individuals with DM are at approximately 1.5–3-fold higher risk of asymptomatic bacteriuria (22). However, there is only one study in the available literature, by Yahata et al from 2022, discussing the application of ATB prophylaxis at the time of the protocol graft biopsy. The result of the given study fully coincides with the conclusion of our analysis (23).

Conclusions

Urinary tract infection is the most frequently occurring complication in the post-transplant period with the risk of developing acute graft rejection and reduced survival of the graft as well as the patient. In addition to the main risk factors for the development of UTI (diabetes mellitus, immunosuppression, ...), mini-invasive procedures performed directly on the uropoetic system (pig-tail extraction, protocol biopsy) have a significant risk potential. The result of our study shows that the administration of ATB prophylaxis at the time of the mentioned procedures does not have a significant protective importance in the context of a positive urine finding, and no risk factor for the development of a positive urine finding or UTI. Based on the results of our analysis, we do not administer ATB prophylaxis at our centre at the time of mini-invasive procedures, thus preventing the development of an increasingly serious medical problem – antibiotic resistance.

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