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Controversy in Antibiotic Prophylaxis during Nephrectomies: Retrospective Study about 471 Procedures

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Abstract

Objectives: To assess the impact of the 2010 update of the French guidelines for Antimicrobial Prophylaxis (ABP) in surgery on Surgical Site Infections (SSI) after nephrectomy.

Methods: A retrospective monocentric study was conducted among patients who had a nephrectomy with ABP (years 2009-2010) and without ABP (years 2013-2014), regardless of the indication. Surgical site infection, based on the definition given by the French guidelines on the prevention of surgical site infections, was the main outcome. Operative time, ASA score and wound class according to the Altemeier classification were recorded and the NNIS (National Nosocomial Infection Surveillance) risk index was calculated for each patient. The other following parameters were also recorded: age, Arterial Hypertension (AHT), diabetes mellitus, smoking, immunosuppression, Body Mass Index (BMI) and Length of Stay (LoS).

Results: A 218 and 253 patients had a nephrectomy in 2009-2010 and 2013-2014 respectively. SSI rates were 1.83% and 8.3% for 2009-2010 and 2013-2014 respectively (p<0.002). No statistical significance were observed concerning the following parameters: AHT, ASA score, smoking, immunosuppression, BMI, age, Altemeier wound class and LoS.

Conclusion: We observed a statistical significant increase of SSI rates in nephrectomy since we stopped systematic ABP in 2011. Further studies are required to identify and rank every parameter that can affect SSI rates in nephrectomy in order to confirm or deny the interest of ABP in nephrectomies.

Keywords: Antibiotic prophylaxis; Surgical site infection; Nephrectomy; Urologic surgery

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Introduction

Surgical Site Infections (SSI) are one of complications that can occur after nephrectomy and have a significant impact on morbidity after urological surgery and increase hospital costs [1-4]. Antibiotic Prophylaxis (ABP) represents one way to prevent SSI in clean-contaminated surgeries and can also be used during clean surgeries under strict conditions. However, the use of ABP in nephrectomies is still unclear as there are controversies whether nephrectomy is to be considered as a clean-contaminated or a clean surgery [5]. European guidelines recommend to use ABP only before Partial Nephrectomy (PN) [1], whereas American guidelines recommend ABP for all nephrectomies [6] and British guidelines in clean contaminated surgeries and not in clean surgeries, but without mentioning which category nephrectomy falls into [7,8]. Concerning French guidelines, since 2010, ABP is not recommended at all, whether before partial or radical nephrectomy [9]. In fact, national and international guidelines concerning the use of ABP in nephrectomy have been extrapolated from other surgeries such as abdominal surgery and are therefore associated with a low level of evidence since there is a lack of randomized clinical trials in this area. Furthermore, existing guidelines initially concerned open nephrectomies, and have been extended to new operating techniques such as laparoscopic nephrectomies or robot-assisted nephrectomies without scientific proof to support this extension [1,2,9-12]. Following the 2010 update of the French guidelines for antimicrobial prophylaxis in surgery, we decided to stop systematic ABP in nephrectomy since 2011. The aim of this retrospective study is to assess the impact of the discontinuation of systematic ABP in nephrectomy in our single institution.

Materials and Methods

Ethics

The protocol was approved by the ethics review committee, and written informed consent was obtained for all patient included in this study. We conducted a monocentric retrospective before-and-after study among patients who underwent nephrectomy during two periods: 2009-2010 when ABP was systematically performed and 2013-2014 without ABP. Inclusion criteria were simple: nephrectomies for tumor (renal carcinoma, renal pelvis neoplasm, oncocytoma or angiomyolipoma) or in order to perform a transplant (kidney donor). Exclusion criteria included positive preoperative urine culture (urinary analysis prior surgery was systematically performed), active antibiotic therapy at the time of surgery, infectious kidney (e.g. pyonephrosis). ICD-9-CM classification (International Classification of Diseases, Ninth Revision, Clinical Modification) was used to identify eligible patients. Nephrectomies included either Radical Nephrectomies (RN) or Partial Nephrectomies (PN), and were performed using one of the following surgical approaches: open, laparoscopic or robot-assisted nephrectomy. According to our protocols, patient who underwent a nephrectomy in 2009-2010 received a 2g cefazolin ABP 30 min before incision followed by a 1g cefazolin injection every 4 h after incision until the surgery was complete. Systematic ABP in nephrectomy was then stopped in 2011 following the 2010 update of the French guidelines for antimicrobial prophylaxis in surgery [9]. Patients who received an ABP formed the “ABP” group whereas patients who did not receive ABP formed the “Ø ABP” group. Primary outcome was SSI rates 30 days after nephrectomy, according to the definition of SSI given by the Center for Disease Control and Prevention (CDC) [13]. SSI diagnosis was based on hospital reports, operative reports, post-operative antibiotic prescriptions, readmission within 30 days reports and post-operative follow-up consultations. Secondary outcomes were post-operative infection rates, compliance with nephrectomy ABP protocol for the years 2009-2010 and nephrectomy distribution by type and surgical approach. Concerning the operative techniques, our urology department acquired a Da Vinci® surgical system (Intuitive Surgical, Sunnyvale USA) in 2010 and progressively was used to perform nephrectomies.

Data collection

Data collection was conducted following the guidelines published by the French SSI surveillance network [14]. The following risk factors were recorded: age, Arterial Hypertension (AHT), diabetes mellitus, smoking, immunosuppression, Body Mass Index (BMI), Length of Stay (LoS), pre-operative LoS, ASA score, operative time and immunosuppression. A patient was considered immunosuppressed if at least one of the following items applied: medication with an immunosuppressive drug (i.e. long term corticosteroid treatment), HIV infection with lymphocyte count <500 CD4+/mm^3, metastatic cancer. Concerning the calculation of the NNIS score, we selected a 75th percentile of 4 h for all nephrectomies, regardless of the type of nephrectomy and the operative technique used [15]. Furthermore, all nephrectomies in this study were considered as clean-contaminated surgeries (i.e. Altemeier wound class II). Finally, conversions and other surgeries realized during the nephrectomy were taken into account. A retrospective surveillance of the ABP was also conducted for the years 2009-2010. Key parameters of the surveillance were: indication, type, timing and duration of ABP.

Table 1: Demographic data.

	ABP		Ø ABP		p
	N	%	N	%	
Nephrectomy	**218**		**253**		
RN	124	-56.90%	138	-54.50%	0.611
PN	94	-43.10%	115	-45.50%	0.611
Male	130	-59.60%	151	-59.70%	0.991
Age (Mean, years)	**61,6 ± 1.9**		**61.0 ± 1.7**		0.623
LoS (d)	**8.3 ± 0.7**		**7.4 ± 0.5**		0.064
RN	7.9 ± 0.9		7.0 ± 0.5		
PN	8.4 ± 1.0		7.9 ± 1.0		
AHT	95	-43.80%	107	-42.30%	0.779
BMI ≥ 30	43	-19.70%	53	(20.9%)	0.742
Diabetes mellitus	21	-9.70%	41	-16.20%	**0.035**
Immunosuppression	21	-9.70%	21	-8.30%	0.613
Smoking	37	-17.10%	44	-17.40%	0.904
Conversion	1	-0.46%	1	-0.40%	1
Complementary Gesture	4	-1.83%	5	-1.98%	1
PreopLoS (mean)	1.07 ± 0.7		0.98 ± 0.5		0.1
ASA score					
1	64	-30.50%	68	-26.80%	0.55
2	118	-56.20%	158	-62.50%	0.068
3	28	-13.30%	26	-10.30%	0.383
4	0	0.00%	1	-0.40%	-
NNIS score					
NNIS 0	166	-76.50%	191	-75.50%	0.869
NNIS 1	46	-21.20%	54	-21.30%	0.949
NNIS 2	5	-2.30%	8	-3.20%	0.566
NNIS 3	0		0		-

ABP: Antibiotic Prophylaxis; AHT: Arterial Hypertension; ASA: American Society of Anesthesiologists; BMI: Body Mass Index; LoS: Length of Stay; NNIS: National Nosocomial Infection Surveillance; PN: Partial Nephrectomy; RN: Radical Nephrectomy

Statistical analysis

Data were expressed as means and standard deviation, as medians or as frequencies, as appropriate. Continuous variables were compared using a t-test, and categorical variables with the Chi-square test or Fischer’s exact test. All analysis and calculations were performed using XLStat® 2014 software. SSI rates were analyzed using a Chi-square test with an 80 percent statistical power. A probability value under 0.05 (two-sided) was thought to be statistically significant.

Results

Demographic data are presented in Table 1. No statistical differences were observed between the two populations regarding age, sex, LoS, operative technique repartition and risk factors except for diabetes mellitus (p=0.035). Kidney tumor was the main indication for nephrectomy (79.4% of all indications). The indication ‘malignant neoplasm of kidney, except renal pelvis’ represented 84% and 89% of the kidney tumors in the “ABP” and “Ø ABP” groups

Table 2: Nephrectomy indications.

	ABP		Ø ABP		
Indication	N	(%)	N	(%)	p
Kidney donor	39	-17.9	42	-16.6	0.695
Unspecified contracted kidney	6	-2.8	10	-4	0.612
Kidney tumor	173	-79.4	201	-79.4	0.98
Malignant neoplasm of kidney, except renal pelvis (renalcarcinoma)	145		179		0.322
Malignant neoplasm of renal pelvis	16		15		0.538
Benign neoplasm of kidney (oncocytoma)	12		7		0.399

ABP: Antibiotic Prophylaxis

Table 3: Surgical approaches.

	ABP		Ø ABP	
	PN	RN	PN	RN
Kidney donor		39		42
Laparoscopy		39		42
Unspecified contracted kidney	1	5*	1	9
Laparoscopy		3		9
Open	1	1	1	
NA		1		
Benign neoplasm of kidney (oncocytoma)	14	2	13	2
Laparoscopy	4		1	1
Robot-assisted	1		9	
Open	9	2	3	1
Malignant neoplasm of renal pelvis	1	11		7
Laparoscopy	1	6		3
Open		5		4
Malignant neoplasm of kidney, except renal pelvis (renalcarcinoma)	78	67	101	78
Laparoscopy	21	32	6	30
Robot-assisted	1		56	5
Open	56	33	39	43
NA		2		
Total	94	124	115	138

ABP: Antibiotic prophylaxis; PN: Partial Nephretomy; RN: Radical Nephrectomy

respectively. No statistical difference was observed between the two groups concerning the indications for nephrectomy (Table 2). Laparoscopic/robot-assisted PN accounted for 27% of all malignant neoplasm of kidney in 2009-2010 vs. 61% in 2013-2014. The proportion of open total nephrectomies (vs. laparoscopic) decreased from 70.2% to 37.4% between the two study periods in favor of laparoscopic nephrectomies. In 2014, robot-assisted procedure was used for 64% of the nephrectomies (PN or RN). Distribution of surgical techniques by indication is presented in Table 3. Significant differences were observed concerning operative times between the two groups. Mean operative time for all nephrectomies was 173.9 min in the 'ABP' group versus 188.9 min in the 'Ø ABP' group (p=0.0036). Focusing on specific procedure, only the operative time concerning open partial nephrectomy differs between the two groups: 162.7 min in the 'ABP' group vs. 201.3 min in the 'Ø ABP' group (p<0.001). The median size of the tumor was significantly higher in the 'Ø ABP' group: 4.7 cm vs. 2.9 cm in the 'ABP' group, explaining the difference in operative times between the two groups. Statistical analysis showed no difference between the two groups concerning RN operative times; all operative times are presented in Table 4. SSI rates were significantly higher in the 'Ø ABP' group compared to the 'ABP' group with 8.3% (n=21) versus 1.83% (n=4) respectively (p=0.003). Most of the SSI occurred in patients who underwent nephrectomy for the indication 'Malignant neoplasm of kidney, except renal pelvis (renal carcinoma)' (n= 17) and who had low predisposition for SSI acquisition (17 patients with NNIS=0; 7 patients with NNIS= 1). Furthermore, SSI occurred equally in RN and PN, regardless of the surgical approach. However, those results were not statistically significative due to the few number of cases. Finally, 33.3% (n=8) of SSI diagnosis were made by the surgeon or a healthcare worker trained in SSI definition and 3 SSI required readmission for specific care of their wound infection. Complete description of all SSI is presented in Table 5 and 6. A total of 25 patients developed an SSI including 4 in the 'ABP' group and 21 in the 'Ø ABP' group. For these 25 patients the median operative time was 180 min similar comparing to the entire population median operative which was 182 min. ABP survey showed that antimicrobial agents consistent with the local guidelines were administered to 96.9% of patients with a correct dose in 92.3% of cases. Overall ABP compliance ranged from 24.6% to 67.2% whether we considered ABP should be administered within 30 min before incision or 60 min respectively. Finally, no ABP exceeded 24 h.

Discussion

This present study showed a significant increase in SSI rates since we stopped systematic ABP in 2011, following the new 2010 French guidelines [9]. The 1.83% SSI rate in the 'ABP' group is in accordance with rates reported in other studies, which are around 2% [16-18]. In contrast, the 8.3% SSI rate found in the 'Ø ABP' group appears to be uncommonly high if nephrectomies are to be considered as clean surgeries, as stated in the French guidelines for antimicrobial prophylaxis in surgery [19]. This study is original since, to our knowledge, Steiner et al. are the only one who assessed SSI rates after nephrectomy as a primary outcome [20]. In their study, the authors conducted a randomized prospective study comparing the efficacy of a single-shot perioperative Ceftriaxone antibiotic prophylaxis, and reported a 0% SSI rate in their ABP group versus 15.9% in the group who did not receive ABP. However, the SSI definition used in their study was not mentioned and the sample sizes were relatively small. One of the major strengths of this present study is that SSI was specifically assessed as a primary outcome using a clear and admitted definition of SSI. Indeed, most of the SSI rates reported in the literature come from studies who assessed SSI as a secondary outcome, without mentioning key elements such as use of an antibiotic prophylaxis, SSI detection protocols, etc. [17,21]. Our study includes other strong features such as the double validation of each SSI case by both the infectious control practitioner and an urologist. Also, our SSI tracking was based on multiple and complementary sources like medical and biological records, post-operative antibiotic prescriptions, and 30 days rehospitalization records and post-operative follow-up visits. Finally, skin preparation protocols remained unchanged during the whole study period including 'ABP' group and Ø ABP' group. Nevertheless, this study presents several limitations. First, significant higher operative times in the 'Ø ABP' group with a mean 15 minutes increase in all nephrectomies (p=0.0036). Since operative time is a well-known risk factor associated with SSI, these significant higher operative times could have led to thinking that it could partially explained the increase in SSI rates. But in fact when compared the operative time of the 25 patients with SSI to the whole population of this study it is similar (180 min and 182 min). Secondly, no specific

Table 4: Operative times.

	ABP group			Ø ABP group			
Operative times	N	Mean (min)	IC_{95}	N	Mean (min)	IC_{95}	P (Student test)
Total nephrectomy	218	173.9	[165.6; 182.2]	253	188.9	[181.7; 196.1]	0.0036
RN	124	180.7	[171.2; 190.2]	138	175.9	[166.8; 185.0]	0.472
Open	41	189.1	[170.8; 207.5]	48	170.8	[154.5; 187.0]	0.133
Laparoscopy/Robot-assisted	80	175.1	[164.3; 185.9]	90	180.3	[169.3; 191.3]	0.506
PN	94	162.7	[149.4; 176.0]	115	201.3	[189.9; 212.6]	<0.001
Open	66	149.9	[136.4; 163.5]	43	192.9	[172.9; 212.9]	<0.001
Laparoscopy/Robot-assisted	27	193	[163.1; 222.9]	72	206.7	[192.9; 220.6]	0.343

ABP: Antibiotic Prophylaxis; PN: Partial Nephrectomy; RN: Radical Nephrectomy

Table 5: Post-operative infections.

	'ABP' group		'Ø ABP' group		
Infection	N	%	N	%	p
SSI	4	1.83	21	8.3	0.002
Superficial incisional	1		10		
Deep incisional	1		9		
Organ/space	2		2		
Urinary	25	11.5	52	20.6	0.008
Respiratory	7	3.21	12	4.74	0.4
Others	6	2.75	11	4.35	0.355

ABP: Antibiotic Prophylaxis; SSI: Surgical site infection

follow-up strategy was implemented in this study: according to the definition, SSI can occur 30 days after surgery, however, establishing and maintaining 30 days follow-up SISA challenging task that requires enormous amounts of time and human resources. This point represents one of the major issues in any SSI study because many tertiary care centers cannot afford to implement SSI surveillance due to those reasons. Furthermore, there are no clear standardized methods for SSI surveillance yet, which makes difficult data collection, comparison between centers and benchmarking attempts [22]. Also, many surveillance methods have been described in the literature that go from standard postoperative antibiotic prescription surveillance to scheduled phone interviews with patients [23-25]. Studies showed that average onset for SSI is 10.9 days and that 12% up to 84% of SSI occur after discharge [18,26,27]. Most of the patients are usually discharged before this time limit, meaning that patients are usually lost to follow-up if surveillance is not efficient enough. Moreover, superficial SSI represent a large proportion of SSI occurring after discharge and these SSI are also often lost to follow-up since they can be easily treated in any primary care facility [18]. The advent of the surgical robot in 2010 also could constituted a bias since it impacted our nephrectomy care algorithm, with robot-assisted nephrectomy

Table 6: SSI characteristics.

	Indication	RN/PN	Surgical approach	SSI	NNIS score	ASA score	Operative time (min)
'ABP' group	Malignant neoplasm of kidney	PN	Open	Superficial Incisional	0	1	170
	Malignant neoplasm of kidney	PN	Open	Organ/space	1	3	175
	Kidney donor	RN	Laparoscopy	Deep incisional	0	1	175
	Malignant neoplasm of renal pelvis	RN	Laparoscopy	Organ/space	0	2	203
'Ø ABP' group	Malignant neoplasm of kidney	PN	Robot-assisted	Deep incisional	1	2	343
	Benign neoplasm of kidney	PN	Robot-assisted	Deep incisional	0	1	209
	Malignant neoplasm of kidney	PN	Open	Deep incisional	0	1	153
	Unspecified contracted kidney	PN	Open	Deep incisional	0	2	231
	Malignant neoplasm of kidney	RN	Open	Super ficial incisional	0	2	135
	Malignant neoplasm of kidney	PN	Robot-assisted	Organ/space	0	2	130
	Malignant neoplasm of kidney	PN	Open	Superficial Incisional	1	3	179
	Kidney donor	RN	Laparscopy	Deep incisional	0	2	125
	Malignant neoplasm of kidney	RN	Open	Super ficial incisional	1	2	251
	Malignant neoplasm of kidney	PN	Robot-assisted	Organ/space	1	2	329
	Malignant neoplasm of kidney	RN	Laparscopy	Deep incisional	1	3	122
	Malignant neoplasm of kidney	RN	Robot-assisted	Deep incisional	0	2	181
	Malignant neoplasm of kidney	PN	Open	Superficial Incisional	0	2	193
	Malignant neoplasm of kidney	RN	Laparscopy	Superficial Incisional	0	2	182
	Malignant neoplasm of kidney	PN	Lobotomy	Deep incisional	0	2	167
	Malignant neoplasm of kidney	PN	Lobotomy	Superficial Incisional	0	2	171
	Malignant neoplasm of kidney	RN	Open	Superficial Incisional	0	2	122
	Malignant neoplasm of kidney	RN	Open	Superficial Incisional	1	3	131
	Malignant neoplasm of kidney	PN	Robot-assisted	Superficial Incisional	0	2	151
	Kidney donor	RN	Laparscopy	Deep incisional	0	1	109
	Malignant neoplasm of kidney	PN	Open	Superficial Incisional	0	2	168

ABP: Antibiotic prophylaxis; ASA: American Society of Anesthesiology; NNIS: National Nosocomial Infection Surveillance; PN: Partial nephrectomy; RN: Radical nephrectomy; SSI: Surgical site infection representing 25% of all nephrectomies in the 'Ø ABP' group at the expense of open nephrectomies. In practice, considering exposure to infectious contamination, one must admitted that robotic approach is definitively equivalent to simple laparoscopic approach: the incisions are equivalent and the instruments and the procedure are nearly the same. Although the impact of robot-assisted nephrectomy in SSI rates is not well-known, several studies have showed that surgical robot was associated with higher PN rates [21,28,29]. On one hand, since PN are considered as clean-contaminated surgeries according to the European guidelines, we could make the assumption that robot-assisted nephrectomy would theoretically be associated with higher SSI rates. On the other hand, surgical robots allow for smaller incisions comparing to open surgery, and most of all, allow suppressing physical contacts between the patient and the operator, which drastically reduce the probability of skin contamination during surgery.

Finally, bacteria responsible for those SSI were not identified since microbiologic analyses of the SSI were not systematically conducted, especially for superficial SSI. These data would have been interesting to identify the source of the infection and the antibiotic resistance profile of the pathogens involved. The 8.3% SSI rate found for the years 2013-2014 raises again the question whether nephrectomies should benefit from ABP. In any cases, our results should be presented to the urologic staff and a multidisciplinary reflection could be engaged on determining how our SSI prevention protocols and operative time could be improved. Also, prospective surveillance of SSI after nephrectomy should be implemented to collect long-term data and follow the evolution of our SSI rates. To conclude, a significant increase in SSI cases after nephrectomy is observed since we stopped systematic ABP in this indication in 2011. This study should be presented to the French and European guidelines panel to implement the discussion whether ABP should be reintroduce or not in the national recommendations. Our work should be pursued and the results we found could be used to set up a double-blind multicenter randomized clinical trial that would be able to collect more robust data and help deciding whether nephrectomy requires ABP. SSI surveillance system should be standardized and a prospective follow up implemented. SSI in nephrectomy is still a controversial subject, and more robust studies are needed to determine whether nephrectomies should be eligible to ABP. ABP remains a medical decision that must be carefully considered even if it is standardized, since poorly managed ABP leads to increased antibiotic consumption, antibiotic resistance, and SSI and Clostridium difficile infections.

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