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Efficiency and safety in using a stainless steel ballast at a peritoneal dialysis catheter tip : the Limousin experience.

Efficacité et sécurité d'utilisation d'une noix de lestage en acier inoxydable du cathéter de Dialyse Péritonéale : l'expérience du Limousin

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Résumé

Objectif : Evaluer le risque de récidive de migration du cathéter de DP après la mise en place d'une noix de lestage. Matériel et méthodes : Etude rétrospective de 1999 à 2014 sur les patients en DP suivis dans la région Limousin comparant deux groupes : groupe lest (mise en place d'un embout en acier inoxydable à l'extrémité intra-péritonéale du cathéter) de 26 patients et groupe témoin de 204 patients. Etait évalué la survenue d'un épisode de migration du cathéter après la mise en place du lest. Les objectifs secondaires étaient (i) de déterminer les facteurs causaux ayant mené au lestage du cathéter, (ii) de s'assurer de l'absence de majoration des complications infectieuses et mécaniques ou d'impact sur les critères d'épuration et la survie du cathéter. Résultats : Plus d'un an après la mise en place du lest, il y avait une absence de récidive de migration dans 86.6% des cas. Il n'y avait pas de majoration du risque infectieux (OR=0.5-IC95% [0.22 ; 1.13]) ou de complications mécaniques (OR=1.77- IC95%[0.77 ; 4.05]). Les critères d'adéquation étaient similaires : KT/V total à 2.37 (groupe témoin) et 2.28 (groupe lest) (p= 0.63). La survie du cathéter lesté était superposable à celle du groupe témoin (p= 0.983). Trois facteurs causaux ont été identifiés : la Dialyse Péritonéale Automatisée (DPA) (OR=0.38-IC95% [0.16 ; 0.9]), l'échec d'emblée de la technique (OR=19.48-IC95% [7.67 ; 49.48]) et une incarcération de l'omentum (OR=15.84-IC95% [5.81 ; 43.21]). Conclusion : L'olive de lestage utilisée semble prévenir la récidive de migration sans qu'il n'y ait de répercussion en termes de complications infectieuses ou mécaniques, ni sur les critères de dialyse ou la survie. Cependant ce cathéter ne dispose pas de marquage CE, ce qui limite actuellement son utilisation.

Mots clés : Dialyse Péritonéale, dysfonctionnement cathéter, cathéter lesté, déplacement cathéter

Summary

Objective: To assess the recurrence of PD catheter migration after the introduction of a walnut ballast. Materials and Methods: Retrospective study from 1999 to 2014 of PD patients followed in Limousin. Were compared two groups: ballast group (patients who benefited from the establishment of stainless steel ballast at the intraperitoneal catheter extremity) with 26 patients and control group with 204 patients. The primary endpoint was the occurrence of an episode catheter's migration after ballast's establishment. Secondary objectives were (i) to determine the causal factors leading to the catheter weighting, (ii) to ensure the safety of the procedure on the following criteria: infectious complications, mechanicals complications, epurations criteria, and catheter's survival. Results: More than one year after the implementation of the ballast, no recurrent migration was observed in 86.6% of cases. It wasn't found an increased risk of infections (OR = 0.5, 95% CI [0.22, 1.13]) or mechanical complications (OR = 1.77- 95% CI [0.77, 4.05]) between the two groups. The adequation criteria were similar: KT / V total : 2.37 in the control group and 2.28 in the ballast group (p = 0.63). The survival of the ballast catheter was comparable among the two groups (p = 0.983). Three causal factors that led to the ballast were identified: automated peritoneal dialysis (APD) (OR = 0.38, 95% CI [0.16, 0.9]), the failure from the first use of the catheter (OR = 19.48, CI 95 % [7.67, 49.48]) and the incarceration of the omentum (OR = 15.84, 95% CI [5.81, 43.21]). Conclusion: The ballast used in these study appears to prevent recurrence of migration, without any impact in terms of infectious or mechanical complications, or on the dialysis criteria or on catheter's survival. However this catheter does currently not have an EC authorization.

Keywords : peritoneal dialysis, catheter malfunction, catheter migration, self locating catheter

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INTRODUCTION

In France, just over 6% of patients undergoing renal replacement therapy are on peritoneal dialysis. However, 8% of hemodialysis transfers are due to a peritoneal dialysis catheter malfunction. The migration of the catheter into the peritoneal cavity may be the cause of these dysfunctions. Although there are several techniques for repositioning the catheter in the small pelvis, these are not always conclusive in the short, medium, or long term. Around 1997, a stainless steel ballast was developed in Limousin (a region in the southwest of France) to be placed at the intraperitoneal tip of the catheter in order to avoid its displacement (1). To determine the effectiveness of this weighting system (called self-locating catheter) in terms of dislocating recurrence and safety of use, we performed a retrospective study of patients who received such treatment.

MATERIAL AND METHODS

This retrospective study was conducted in patients followed by peritoneal dialysis in Limousin. The data collected included all patients who received a peritoneal dialysis catheter (control group) and those who, after an episode of catheter dislocation, had benefited from the introduction of a so-called self-locating catheter (ballast group). Data were collected from the patients' medical records. The first publication of the weighting nut used in this study dates from September 1999, and the present report extends from this dating to May 1, 2014.

The primary objective was to assess the risk of catheter dislocation recurrence, using a self-locating catheter after a catheter migration episode with a conventional non-ballast catheter. The primary endpoint was the occurrence of an episode of catheter migration into the abdominal cavity after the addition of a weighting ballast to the catheter.

The secondary objectives were to determine causal factors leading to the need of using a catheter with ballast and to evaluate the safety of the ballasted catheter in terms of mechanical complications, infectiousness, and the adequacy and survival of the technique. The catheters were surgically placed by four experienced surgeons. These same surgeons placed the catheters and fixed to them the ballast when needed. These were straight Tenckhoff catheters in the city of Limoges and swan-neck Tenckhoff catheters in the city of Brive. The weighting system is a stainless steel olive weighing 15g, equipped with a tip with clamping nuts and placed at the intraperitoneal end of the catheter (Figure 1). It was made by Dussartre

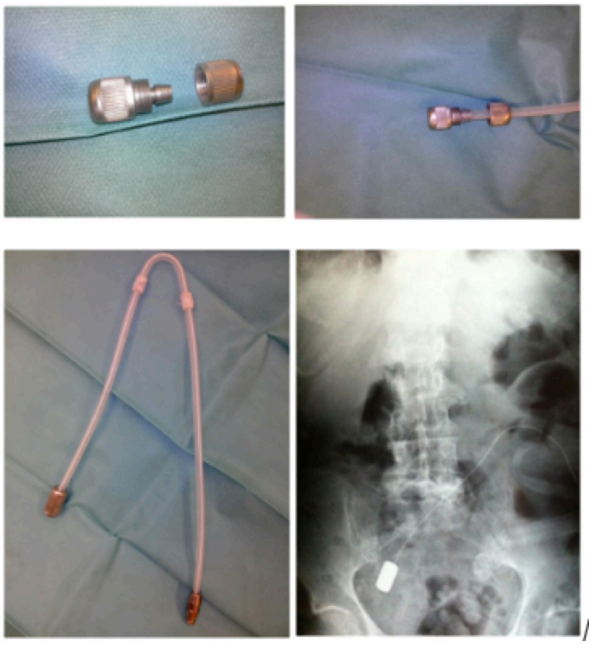

Figure 1 : Stainless steel ballast used in the study

Company in Haute-Vienne. Although the introduction of the olive required a new surgical procedure, it did not require the introduction of a new catheter.
The statistical analysis was done using the R software. For the main endpoint we used a Kaplan Meier survival curve to determine migration-free catheter survival at a time of "t" (t being by default the day of the analysis statistics). For each of the secondary endpoints, we looked separately at whether there were significant differences between the ballast and control groups: a logistic regression was used to search for causal factors and for the evaluation of infectious and mechanical complications. In the case where there was little or no event in one of the two groups, an exact test of Fischer and / or a χ^2 was used. For dialysis adequacy criteria a multiple linear regression system was adopted. A student's t test was required for average comparisons. When comparing categorical data a χ^2 test was used.

RESULTS

Study population

The flowchart (Figure 2) represents the achievement of the study population. In the end, statistical analyzes were conducted on 230 patients (252 catheters): 204 patients with an unweighted catheter and 26 patients with a ballasted dialysis catheter. One hundred and fifty-five patients (168 catheters) were excluded (three catheters placed outside the region, 152 files with too much missing data).The epidemiological characteristics of the entire population and of each group are summarized in the

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tables referred to (Tables I and II). The distribution of males and females was similar across the cohort. The average age was 68.25 years (17–96 years). In addition, there were significantly more patients in CAPD than in APD, but the distribution within groups was similar, although the proportion of CAPD patients appeared to be greater in the control group (p = 0.04159). Statistically significant, there were more patients with no weighted catheter in Limoges compared to Brive (p = 0.0048). Patients in the ballast group appeared to have a lower BMI (21.4 kg/m²) than those in the control group (25.1 kg/m²) (p = 0.0458-95% CI [0.05, 4.77]). There was significantly more incarceration of the omentum and at least one migration episode in the ballast group (p <0.0001).

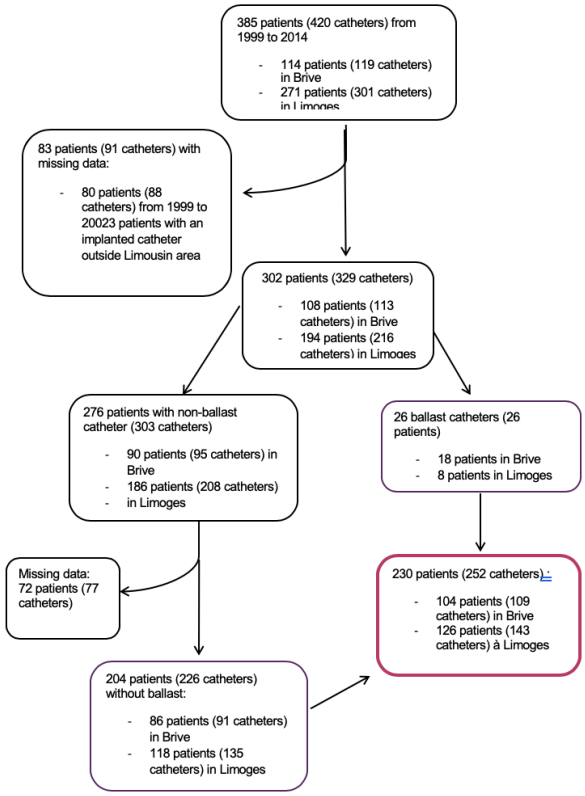

Figure 2 : Diagramme de flux de l'étude

Of the 26 patients who received a ballast, three (11.5%) had a recurrence of migration. The average time to recurrence after ballasting was 175.3 days (26–443 days). The incidence rate of new catheter migration was approximately 0.007 or 0.7 catheters loss per 100 patient-months. In the analysis of migration-free survival at time «t,» there was no further catheter migration in 95.8% of cases at 26 days (0.958, 95% CI [0.0408–1]) and in 86.6% of

Table I: Epidemiological characteristics of the entire cohort

	Total (n = 230)
City (L/B)	126/104 (54.8/45.2%)
Sex (M/F)	131/99 (57/43%)
Age (years)	72
	Total (n = 252)
Technique : APD/CAPD	109/143 (43.3/56.7%)
Laterality : R/L (n=241)	60/181 (24.9/75.1%)
Abdominal surgery	120 (52.2%)
Hernia(s) treatment	30 (13%)
Hemodialysis need	15 (6%)
Omentum incarceration	22 (8.7%)
Lest	26 (10.3%)
Migration	53 (21%)

Table II: Demographic characteristics of the two study groups recurrence of the migration after the installation of a ballast

	Control group (n= 204)	**Ballart gtoup (n= 26)**	**P value**
City (L/B)	118/86 (57.8/42.2%)	8/18 (30.8/69.2%)	0.0048
See (M/F)	117/87 (57.4/42.6%)	14/12 (53/46%)	0.8531
Néphropathy			
Diabetic	30 (14.7%)	1 (3.8%)	0.1284
Vascular	57 (27.9%)	4 (15.4%)	0.1759
Mixte	28 (13.7%)	3 (11.5%)	0.7169
Glomerular	37 (18.1%)	7 (26.9%)	0.3091
Tubulo Interstitial	18 (8.8%)	5 (19.2%)	0.09364
Polykystosis	10 (4.9%)	1 (3.8%)	0.816
Others	24 (11.8%)	5 (19.2%)	0.2754
	Control group (n= 226)	**Ballast group (n= 26)**	**P value**
Age (years)	69	67.5	0.3749
BMI (kg/m²)	25.1	21.4	0.0458
Technique (APD/CAPD)	96/138 (42.5/61.1%)	16/9 (61.5/34.6%)	0.04159
Laterality (R/L)	52/165 (23/73%)	8/16 (30.8/61.5%)	0.379
Abdominal surgery	105 (51.5%)	15 (57.7%)	0.2775
Hernia repair(s)	27 (13.2%)	3 (11.5%)	0.9514
Omentum incarceration	11 (4.9%)	11 (42.3%)	<0.0001
Migration total	36 (14.2%)	22(80.8%)	<0.0001
Replacement by cœlioscopy exclusively	14 (6.2%)	4 (15.4%)	0.08807

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cases at 443 days (0.866, 95% CI [0.0727–1]) (Table III). The life duration of the catheter before placement of the ballast was on average 234 days (7.7 months), while the life duration of the catheter after placement of the ballast was 511 days (16.8 months).

Table III: Survival without weighted catheter migration

Patients	Delay ballast-récidive (days)	Survival	IC 95%
MC	26	0.958	[0.0408–1]
TK	57	0.917	[0.0564–1]
BH	443	0.866	[0.0727–1]

Results on the secondary endpoints

Causal factors of catheter ballast use

Statistically significant, CAPD was protective (0.38, 95% CI [0.16–0.9]) even after removing a possible city-related effect (0.3, 95% CI [0.12–0.72]). It would be 3.3 times more likely to have a weighted catheter when the patient was on APD compared to CAPD. The use of a ballast was significantly greater following incarceration of the omentum in the catheter (OR = 15.84, 95% CI [5.81–43.21]). Failure to initiate the technique was significantly greater in the ballast group with an Odds Ratio (OR) of 19.48 [95% CI: 7.67–49.48], with, however, a city effect. Indeed, there was seven times less failure in the initiation of the technique in Limoges compared to Brive. Not significantly, patients with lower BMIs had more use of ballast (OR = 0.9, 95% CI [0.81–1]). The increase of 1 kg/m² BMI could be associated with a decrease of 1.1 times the risk of using a ballast. A 0.5-fold increase in this risk was observed when the catheter was placed using the Moncrief-Popovich method (buried catheter) (OR = 2.01, 95% CI [0.79, 5.14]). Regarding the site of implantation of the catheter, the history of abdominal surgery, the completion of hernia repair(s) during the placement of the catheter, or the delay between the date of catheter implantation and the initiation of the method, there were no significant differences between the two groups (Table IV).

Complications, adequacy, survival of the technique

The number of peritonitis and exit-site infections appeared to be similar in both groups (Table V). In the logistic regression analysis, no more infectious complications were found in the ballast group compared to the control group. This is as true for infections as a whole (OR = 0.5–95% CI [0.22, 1.13]) as for dialysis fluid infections (OR = 0.5827–95% CI [0.24, 1.42]), tunnel infections (OR = 0.2921–95% CI [0.04; 2.24]), or exit-site infections (0.–95% CI [0.15; 1.10]) (Table VI).

Table IV: Causal factors for setting up a ballast according to a logistic regression

Studied causal factor	OR [IC 95%]
Laterality : left versus right	0.67 (0.28; 1.64)
Technique : CAPD versus APD	0.38 (0.16 ; 0.9)
Abdominal surgery antecedent	1.57 (0.69; 3.57)
Hernia(s) repair	0.96 (0.27; 3.42)
BMI	0.9 (0.81; 1)
Embedded catheter	2.01 (0.79; 5.14)
Initial failure	19.48 (7.67; 49.48)
Omentum incarceration	15.84 (5.81; 43.21)

The logistic regression analysis showed no difference between the two groups, either for all the mechanical complications (OR = 1.77–95% CI [0.77; 4.05]) or for those taken one by one: hernias (OR = 1.751–95% CI [0.5517; 5.558]), peri-catheter leaks (OR = 0.78–95% CI [0.1; 6.28]), extrusion of the outer cuff (OR = 6.17–IC 95 % [0.98, 38.75]), and flow problems other than catheter migration (OR = 1.23 [0.4; 3.82]. An exact Fischer

Table V : Epidemiological characteristics in terms of infection, mechanical complications, and adequacy for the two groups studied (control and ballast)

	Control group (n= 226)	Ballast group (n= 26)	Total (n = 252)
Infections			
Peritonitis	133 (58.8%)	7 (26.9%)	140 (55.5%)
Tunnel infections	29 (12.8%)	1 (3.8%)	30 (11.9%)
Exit site	128 (56.6%)	6 (23.1%)	134 (53.2%)
Mechanical			
Hernia	22 (9.7%)	5 (19.2%)	27 (10.7%)
Leakage	11 (4.9%)	1 (3.8%)	12 (4.8%)
Hyper-pressure	13 (5.8%)	0 (0%)	13 (5.2%)
Dialysate flow problem	29 (12.8%)	4 (15.4%)	33 (13.1%)

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Table VI: Comparison of the two groups in the occurrence of infectious and mechanical complications

Studied complications	OR (IC 95%)
Total infections	0.5 (0.22; 1.13)
	OR (IC 97.5%)
Peritonitis	0.5827 (0.24; 1.42)
Tunnel infection	0.2921 (0.04; 2.24)
Exit-site infections	0.4017 (0.15; 1.10)
	OR (IC 95%)
Total mechanical complications	1.77 [0.77; 4.05]
Hernias	1.751 [0.5517; 5.558]
Peri-catheter leak	0.78 [0.1; 6.28]
External cuff extrusion	6.17 [0.98; 38.75]
Intra-abdominal hyperpressure	NA

test showed no significant difference between the two groups (p = 0.3724) in terms of intra-abdominal hyper-pressure problems.

As for the dialysis adequacy parameters for the ballast group, the analyses could only be carried out on the results after the implementation of the ballast (Table VII). Indeed, only one patient had been able to benefit from a dialysis adequacy test before the introduction of the ballast. The mean overall KT / V was 2.37 (± 0.72) in the control group and 2.28 (± 0.55) in the ballast group. There was no significant difference between the two groups for all of the adequacy criteria, with the exception of the weekly clearance of dialysate creatinine (p = 0.012). It was not possible to compare peritoneal permeabilities with too many missing data.

Regarding the survival of the technique, at the time of analysis, there were 37 live patients in the control group (14.7%) and four live patients in the ballast group (15.3%). The mean duration of treatment was 594 days (1.6 years); the median was 1.2 years in the control group and 532 days (1.5 years) and 0.8 years [49 days–4.3 years] respectively in the group ballast. There was no statistically significant difference (p = 0.7935) in terms of duration of treatment or in terms of the reasons for stopping the technique (death, renal transplantation, withdrawal to hemodialysis for inadequacy, dysfunction of the catheter, or infection).

Table VII: Averages and comparison of treatment criteria between the two groups (Cl creatine: weekly clearance of creatinine in L/wk/1.73m², FRR: residual renal function in ml/min).

Studied variables	Means in control group	Means in ballast group	p-value
KT/V total	2.37 (± 0.72)	2.28 (± 0.55)	0.63
KT/V dialysate	1.44 (± 0.33)	1.35 (± 0.26)	0.34
KT/V residual	0.94 (± 0.70)	1.02 (± 0.49)	0.66
Total creatinine clearance	91.14 (± 37.28)	80.8 (± 22.18)	0.29
Dialysis creatinine clearance	37.63 (± 12.42)	29.4 (± 9.67)	0.012
Kidney residual creatinine clearance	53.5 (± 38.19)	51.5 (± 23.78)	0.84
Residual renal function	5.82 (± 3.86)	5.07 (± 2.87)	0.48

As shown in Figure 3, the survival of the weighted dialysis catheter is not inferior to that of an unweighted catheter (p = 0.983).

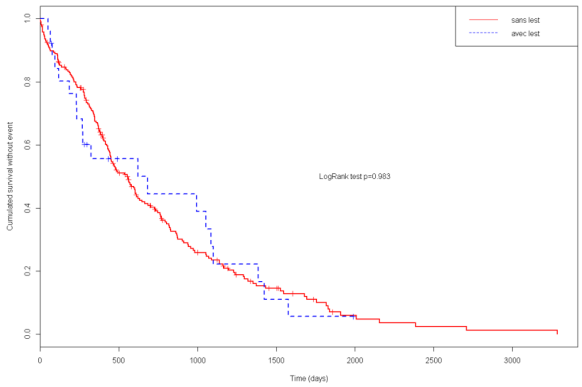

Figure 3 : Survival curve of dialysis catheters in the control group (red) and the ballast group (blue)

DISCUSSION

The migration of the catheter out of its original position is a frequent complication of peritoneal dialysis and not inconsequential. Several techniques are available to reposition it in the lower abdominal area. Setting up a ballast may be a solution. Indeed, in this study, a recurrence of migration was observed in only three of our 26 patients (11.5%). At 26, 57, and 443 days, the absence of recurrence of migration was found at 95.8, 91.7, and 86.6% respectively. In the ballast group, the percentage of migration before ballast was 80.8% and decreased by a factor of 7 after ballast. In the control group this percentage was 14.2%. In 1993, Di Paolo et al. presented for

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the first time a new type of catheter called «self-locating catheter» (2) based on the same principle and leading to the completion of several studies. The Tenckhoff-type straight catheter was compared to the self-locating catheter. The results showed a significant superiority of the self-locating catheter compared to the conventional catheter with respect to the various complications studied (3). Spanish teams have also experimented with this type of catheter by comparing it with not only Tenckhoff's catheter but also the «coil» catheter. The self-locating catheter group had statistically significantly survival and less migration occurrence (4). Bergamin et al. in Switzerland obtained the same findings (5). Other methods have been explored to limit the displacement of the catheter in the peritoneal cavity: the internal fixation of the catheter to the abdominal wall by nonabsorbable wire (6), the Mayo Clinic doctors attached a testicular prosthesis to the distal end of the catheter, the latter having the role of ballast (7). In the prospective study of Di Paolo et al. (2) (3), the self-locating catheter had 0.8% migration compared to 12% in their control group in a statistically significant manner. Our percentage migration in the control group of 11.5%, is superimposable to their study. However, patients on peritoneal dialysis did not systematically benefit from an abdomen X-ray without preparation at the initiation of the technique or in follow-up. A certain number of migrations could thus have gone unnoticed in the absence of symptomatology. It would have been interesting to know exactly how many patients who had a catheter migration. Routinely performing an abdominal X-Ray without preparation could have helped to determine the risk factors for dialysis catheter migration, to more accurately analyze the survival of migrated and weighted catheters relative to the rest of the population.

The Italian study shows an overall survival curve at 14 months of about 93%. The Swiss study (5) had an overall survival of about 80% at the same time. In our cohort, the survival of the ballast group is of the same order. In the Swiss study, the incidence rate without catheter dysfunction was 0.01 catheter per month spent on PD (approximately the loss of one catheter per 100 patients/month). In our study this rate was 0.007 (i.e., loss of 0.7 catheter per 100 patients/month). The «self-locating catheter» seems to have proved its interest (2) (3) (4) (5) and its safety in the various studies where it has been studied and has the advantage of having a CE marking, which is not the case of the ballast studied here. The introduction of a weighted catheter seems to retain its advantages even in case of previous surgical procedures (17).

In addition, fluoroscopic or laparoscopic repositioning techniques have variable rates of failure and relapse (8) (9). In Simon's study, the initial success rate increased from 85% to 50% at 30 days (9). The absence of recurrence in our study seems much more durable in the long term. However, it was noted that there was little attempt at repositioning and laparoscopy. No notion of laxative therapy was found to try to reposition the catheter. It is possible that this information was not collected in the file. The few identified patients (fewer than 10 patients in total) to benefit from repositioning using «conventional» methods did not allow us to compare them with those who received a ballast. In five patients who had this type of technique, they finally benefited from the implementation of the ballast.

The causes of catheter migration are poorly detailed in the literature. The superiority of one catheter over another is still subject to debate, although «coil» catheters appear to be causing more migration (10). In the literature, the incarceration of the omentum seems to be involved in 35 to 80% of cases according to the series (11), followed by the presence of intraperitoneal adhesions. The patient with the shortest post-ballast migration recurrence had a lot of adhesions. In contrast, buried catheters do not appear to be associated with an increased risk of migration or catheter dysfunction (12) (13), particularly in terms of incarceration of the omentum or obstruction with fibrin (14). Note that these considerations seem to be revisited if the catheter remains buried for too long (15). Moreover, the quality and the habit of the surgical gesture seem to be two crucial points. The literature tells us that patients with a smaller body surface area and a lower BMI would tend to have more catheter dysfunction (16). Our results are similar: patients with lower BMIs were more likely to have a ballast, but with no statistically significant difference. The flow rate and intraperitoneal flow imposed on the catheter is greater in APD, which may explain why patients with APD have benefited more from the introduction of a ballast. In addition, it is recognized that the position of the catheter must be optimum in APD, the latter taking place at night in an extended position.
Infectious complications represent the first cause of discontinuation of the technique. The overall incidence of infection in the weight group was 0.1 patient-months before the introduction of the ballast and 0.01 patient-months after the introduction of it. In the control group, the occurrence of this event was 0.06 patient-months. The introduction of the ballast, although requiring a new surgical procedure, is therefore not associated with an increase in the rate of infection. In the studies conducted by Di Paolo and Bergamin, a reduction in the infection rate was observed in the group of patients carrying the self-locating catheter. The occurrence of mechanical

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complications was not increased by the introduction of the ballast olive, and the occurrence of these types of complications was similar to those obtained in the literature.

This study has several negative points. Since this is a retrospective study, it is always difficult to compare the cases with the controls without forgetting that there is a memory bias (missing data). The study spans a period of 15 years, during which practices and consideration of peritoneal dialysis has shown changes and advancements. Patients are therefore not strictly comparable over time. Finally, the sample of the ballast group includes only a small number of individuals compared to the rest of the population, which can be a source of misinterpretation. Indeed, for the analysis of the main judgment criterion a nonparametric test was preferred in front of a small number in the ballast group, in order to maintain a certain robustness and to accept losing power.

CONCLUSION

Using a ballast olive to keep the catheter in the pelvic position may be a solution. In this study, we observed an absence of recurrence of migration in 86.6% of cases beyond 15 months. In addition, catheter ballasting does not appear to be associated with an increase in infectious complications or other mechanical complications. Currently, the ballast used does not bear the CE (European Conformity to Requirements) marking. Since a self-locating catheter has already been developed, has demonstrated its effectiveness, and is already marketed, the use of the catheter seems more acceptable, especially if it exists. Predictive factors for dysfunction such as the use of APD, a low BMI or if the catheter is going to be buried.

CONFLITS D'INTERET

The authors declare that they have no conflict of interest for this article

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