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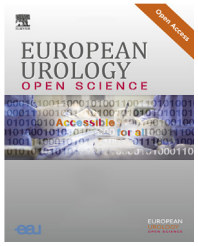

Pediatric Urology

Day Surgery in Children Undergoing Retroperitoneal Robot-assisted Laparoscopic Pyeloplasty: Is It Safe and Feasible?

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Abstract

Background: Robot-assisted pyeloplasty is the most frequently performed robotic procedure in children. A retroperitoneal approach limits surgical trauma and avoids peritoneal irritation. This led to the establishment of the criteria for day surgery (DS) and a related clinical care pathway.
Objective: To assess the feasibility and safety of DS in children undergoing retroperitoneal robot-assisted laparoscopic pyeloplasty (R-RALP).
Design, setting, and participants: We performed a bicentric prospective study (NCT03274050) over 2 yr involving the two major paediatric urology teaching hospitals in Paris. A clinical pathway and a prospective research protocol were specifically established.
Intervention: DS in selected children undergoing R-RALP.
Outcome measurements and statistical analysis: The primary outcomes were DS failure, 30-d complications, and readmission rates. The secondary outcomes included preoperative characteristics, perioperative parameters, and surgical outcomes. Quantitative variables were expressed as medians with interquartile ranges.
Results and limitations: Thirty-two children fulfilled specific inclusion criteria and were consecutively selected for DS following R-RALP. The median patient age was 7.6 yr (4.1–11.8) and weight 25 kg (14–45). The median console time was 137 min (108–167). There were no intraoperative complications or conversions. Six children were kept under observation overnight and discharged the following day due to persistent pain (n = 3), parental anxiety (n = 2), or a prolonged procedure (n = 1). The median duration of hospital stay of the 26 children in the DS setting was 12.7 h (12.2–13.2). During the 30-d period, there were four emergency room

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visits (15%) resulting in two patients requiring readmission (8%): one for febrile urinary tract infection (Clavien-Dindo II) and one child with no JJ stent for urinoma (Clavien-Dindo IIIb). Radiological studies confirmed improvement in dilatation for all cases with no recurrence (median follow-up: 15 mo).

Conclusions: This prospective case series is the first to demonstrate the feasibility and safety of DS in children undergoing R-RALP, obviating the need for routine inpatient care. Excellent results can be achieved by careful patient selection, a clear clinical pathway, and a dedicated team. Further evaluation is warranted to assess the cost effectiveness.

Patient summary: This study shows that day surgery after robotic pyeloplasty is both safe and effective in selected children.

1. Introduction

Increasing experience and surgical advances have allowed more laparoscopic procedures in children to be performed as day surgery (DS), for example, appendectomy, cholecystectomy, and nephrectomy [1–3]. The benefits of DS are well recognised for the child, family, and health system [4]. It results in quality and safe care, greater parental satisfaction [5], reduced hospital-related fear for the child [6], and prevention of nosocomial infections [7,8]. Furthermore, the economic justification (eg, reduced hospital stay and bed occupancy) benefits not only the health care system, but also the current and future patients through the opportunity costs gained [9–11]. For these reasons, DS has become a health care priority in France for over a decade [12], with a goal that 70% of surgical procedures be performed as DS by 2022. This revolution requires the broadening of criteria for DS, but within a well-defined and robust evidence base. Guidelines regarding inclusion criteria, patient/family education, discharge protocols, and establishment of a dedicated multidisciplinary care team are also required.

In paediatric urology, laparoscopic DS has become the standard of care for orchidopexy, inguinal hernia repair, and varicocelectomy [13]. There is a growing body of evidence that robotic surgery for more complex conditions can also be performed in a DS setting [14–16]. The herald of minimally invasive surgery (MIS) in pyeloplasty was associated with increased operative times [17], but robotic approaches have solved many of the problems associated with conventional laparoscopy [18,19]. Robot-assisted laparoscopic pyeloplasty (RALP) has increasingly been utilised over the past decade [20], resulting in shorter operative times and significantly shorter hospital stays [19].

Our preliminary experience with retroperitoneal robot-assisted laparoscopic pyeloplasty (R-RALP) in children demonstrated a significantly shorter recovery time over the transperitoneal approach (92% of children discharged on day 1) [21]. This probably relates to reduced surgical trauma and avoidance of peritoneal irritation. This initial experience led to the establishment of criteria for DS and a related clinical care pathway. However, paediatric RALP as DS has not yet been studied widely.

The objective of the current bicentric prospective study was to establish the safety and feasibility of DS in children undergoing R-RALP. We also sought to define a set of criteria to assist appropriate patient selection for DS surgery.

2. Patients and methods

We performed a prospective cohort study over 2 yr (July 2020–June 2022) across the two major paediatric urology teaching hospitals in Paris. The study received approval from an independent ethics committee (Comité de Protection des Personnes, CPP Ile de France VII). The sponsor was Assistance Publique-Hôpitaux de Paris (Clinical Research and Innovation Delegation), and the project was funded by a grant from Necker Hospital. It was registered with the ClinicalTrials.gov identifier NCT03274050.

Both centres were experts in MIS and robotic surgery, and favoured a retroperitoneal approach to pyeloplasty. Based on a previously published algorithm for ureteropelvic junction obstruction, we excluded children who were younger than 2 yr of age (with preference for posterior lumbotomy or retroperitoneal laparoscopy), were undergoing redo surgery for secondary ureteropelvic junction obstruction, had horseshoe kidney, had renal ectopia, or were undergoing ureterocalicostomy [22]. Children undergoing R-RALP and meeting the criteria for DS were included in the study. The inclusion criteria for DS following R-RALP are presented in Table 1. The preoperative exclusion criteria were solitary kidney, horseshoe kidney, and ectopic kidney (requiring a transperitoneal approach), significant associated comorbidities, and major social difficulties. DS failure was defined by the absence of discharge on the day of surgery where this was scheduled initially. All parents were aware of the option of staying overnight at any point in the care pathway if needed. During the preoperative outpatient clinic appointment, if parents were not comfortable with the plan for a DS procedure, they were not included in the study. During the preoperative period, prescriptions for postoperative analgesia were provided and collected by the family.

Procedures were performed by three senior surgeons (each having >10 yr of experience in complex reconstructive laparoscopy) and three supervised fellows. The diagnosis of pelviureteric junction obstruction was confirmed by renal ultrasound and technetium Tc 99m mercaptoacetyltriglycine-3 (MAG-3) renal scan, or uro–magnetic resonance imaging with functional evaluation. Indications for surgery in asymptomatic children were reduced renal function on renal scan (defined as >5% loss of function observed between two consecutive renal scans) and/or increasing hydronephrosis on ultrasound. Children with equal differential renal function (DRF) and symptoms (eg, ipsilateral

Table 1 – Defined pre-, intra-, and postoperative criteria for day surgery in children following R-RALP

1.	Preoperative criteria:
	(a) Parental informed consent
	(b) Family home within 150 km of the hospital
	(c) Child over 2 yr of age
	(d) Primary pelviureteric junction obstruction (eg, not recurrent cases)
2.	Intraoperative criteria:
	(a) First case on a morning list
	(b) Robotic surgery completed by 1:00 PM
	(c) Uneventful intraoperative course
	(d) Removal of urinary catheter at the end of the procedure
	(e) No perirenal drainage tube required
3.	Postoperative criteria:
	(a) No immediate postoperative complications
	(b) Haemodynamically stable in recovery
	(c) Ambulating without significant difficulty
	(d) Tolerating oral fluids
	(e) Pain controlled on oral analgesics
	(f) Children were required to void prior to discharge

R-RALP = retroperitoneal robot-assisted laparoscopic pyeloplasty.

flank pain and/or recurrent febrile urinary tract infections (UTIs), and high blood pressure) were also offered surgery. Children who were diagnosed after a UTI underwent a voiding cystourethrogram preoperatively.

2.1. Surgical technique

As reported previously, patient positioning and the surgical technique for R-RALP were standardised [22] utilising the Da Vinci Xi robot platform (Intuitive Surgical, USA). A single perioperative dose of ceftriaxone (50 mg/kg) was given. Three 8-mm robotic ports and one 8-mm assistant port were placed. Pelviureteric anastomosis was performed with a 6/0 monofilament absorbable continuous suture using a 3/8-circle needle (Anderson-Hynes pyeloplasty). After finishing the anterior line of anastomosis, we inserted either a one blind-ending or Magnetic Black-Star Urotech 4.7F polyurethane double-J stent through the assistant trocar positioned in an anterograde fashion, or an external ureteropelvic stent. The external stent was connected to a drainage bag and removed on day 10 in the outpatient clinic. If a double-J stent was used, it was scheduled for removal after 4 wk in the outpatient clinic. In cases of aberrant polar vessels, the ureter was completely divided, and the ureteropelvic junction and pelvis were delivered anterior to the vessels with the help of the stay suture. The anastomosis was then performed as described previously.

2.2. Anaesthetic and analgesic management

General anaesthetic was provided according to a common protocol. All patients underwent 3 min of preoxygenation, and induction was performed using sevoflurane (6% in a mixture of O_2/N_2O 50%/50%) or intravenous propofol (5–7 mg/kg). All patients were intubated, and a nondepolarising muscle relaxant was administered. Intraoperative opioid analgesics were given to all patients (sufentanil 0.2 μg/kg initial bolus, 0.1 μg/kg reinjection) according to variations in heart rate and blood pressure. Prevention of postoperative nausea and vomiting begin after induction using dexamethasone (0.15 mg/kg) and ondansetron (0.1 mg/kg). Ropivacaine (2%) was injected subcutaneously around the trocar sites at the end of the procedure. No regional blocks were performed. Muscle relaxation was systemically reversed at the end of surgery. At the end of the procedure, the staff anaesthesiologist was asked to confirm that there were no anaesthetic-related contraindications to DS.

Postoperative analgesics administered in the postanaesthesia care unit (PACU) were based on local protocols and consisted of nonopioid analgesics (paracetamol 15 mg/kg, and ketorolac 1 mg/kg) and rescue analgesics if required (nalbuphine administered as a 0.2 mg/kg bolus). Discharge to the stepdown observation unit was at the discretion of the staff anaesthesiologist. The same protocols were used across the two centres with regard to postoperative care, discharge pathways, and pain control. In each instance, the operating surgeon evaluated the clinical status of the patient 3–4 h postoperatively to assess appropriateness for discharge.

On discharge, parents were advised to administer paracetamol and nonsteroidal anti-inflammatory drugs at scheduled times for 48 h. No opioid analgesics or prophylactic antibiotics were prescribed. Routine instructions (wound care, diet, bathing, activity restrictions, return to day-care/school, etc.) were reviewed with families before discharge. The family was given a direct contact number for the operating surgeon or on-call surgeon in case of an emergency. The surgeon contacted the family on the 1st postoperative day to review clinical status (oral intake, pain control and use of analgesics, constitutional symptoms, and voiding) and to ensure continued well-being. On day 7, parental satisfaction was evaluated and families were asked about the use of analgesics. Our standard postoperative follow-up after R-RALP remains unchanged [22].

Success was considered objectively as resolution of clinical symptoms, decrease of hydronephrosis on ultrasonography (anteroposterior diameter of renal pelvis and diameter of calices), and improved drainage on MAG-3 without further impairment of renal function in patients who had reduced DRF preoperatively.

2.3. Statistical analysis

The primary outcomes were DS failure, 30-d complication rates, 30-d emergency room (ER) visits, and readmission rates. The secondary outcomes were preoperative characteristics, perioperative parameters, surgical outcomes, and family satisfaction regarding the clinical pathway. Statistical analysis was performed using R 4.0.3 software (http://cran.r-project.org). Continuous variables are expressed as medians and interquartile ranges (IQRs; 25th and 75th percentiles), and categorical variables as numbers and percentages.

3. Results

Since the beginning of the multidisciplinary paediatric robotic programme at Hôpital Necker-Enfants Malades (2016) and Hôpital Robert Debré (2019), 137 cases of R-RALP have been performed. Since the beginning of the study period in July 2020, 54 cases of R-RALP were performed and 33 cases fulfilled the inclusion criteria (Fig. 1). Only one family declined DS during outpatient consultation, and therefore the child was not included.

During the study period, 29 children were operated with the open approach (median age 0.4 yr [IQR 0.3–0.8]) and 14 with the retroperitoneal laparoscopic approach (median age 0.6 [IQR 0.3–3.2]).

Table 2 shows baseline demographics and indications for surgery, and Table 3 shows the surgical variables of the cohort. Ten children had DRF below 45%, ranging from 13% to 42%. The median console time was 137 min (108–167). No intraoperative complications were encountered, and there was no need to convert to open surgery. Six children were kept under observation overnight and discharged the following day. Interestingly, all of them received only paracetamol overnight in hospital.

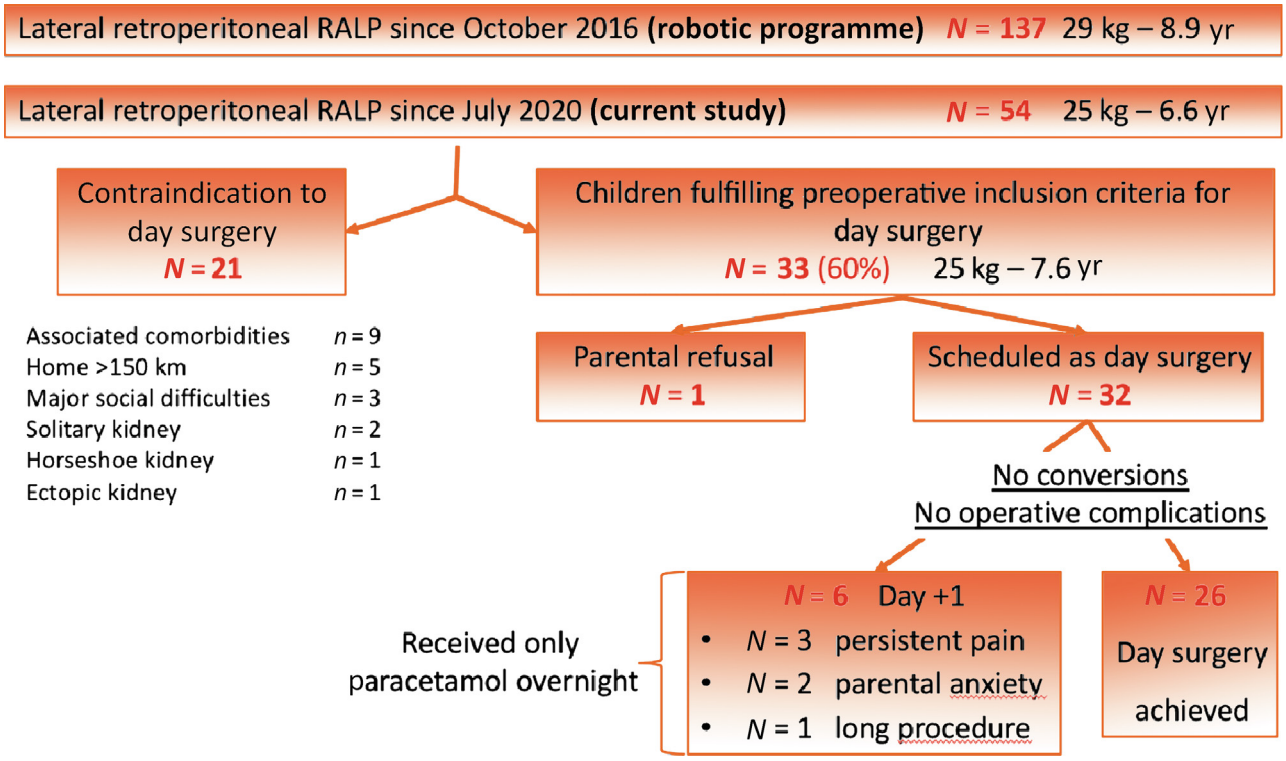

Fig. 1 – Flowchart of the study population. RALP = robot-assisted laparoscopic pyeloplasty.

The median hospital stay for the 26 children undergoing DS was 12.7 h (12.2–13.2). This can be subdivided into (medians):

1. Preoperative ward time: 1 h
2. Operative room time: 5 h
3. PACU time: 3 h 30 min
4. Stepdown observation unit time before discharge: 3 h

At home, all patients were taking analgesics as prescribed and on schedule with good pain control. No child required medication beyond day 4. During the 30-d follow-up period, there were four ER visits (15%) including two readmissions (8%):

1. One had febrile UTI (Clavien-Dindo II).
2. One 2-yr-old girl had a double-J stent malpositioning (distal end of the stent visible at the vulva); the stent was removed. She represented with abdominal pain 3 d after surgery. A large urinoma secondary to anastomotic leak was diagnosed and drained percutaneously under general anaesthetic, and a double-J stent was inserted (Clavien-Dindo IIIb).

Ultrasound showed a decrease in hydronephrosis in all cases on regular follow-up (median preoperative renal pel-

Table 2 – Demographics of the study cohort and indications for surgery

	R–RALP (*n* = 32)
Age (yr)	7.6 (4.1–11.8)
Gender, *n* (%)	
Male	18 (56)
Female	14 (44)
Weight (kg)	25 (14–45)
Indication for surgery, *n* (%)	
Pain	20 (62)
Prenatal hydronephrosis	5 (16)
Postnatal hydronephrosis	2 (6)
Urinary tract infection	5 (16)
Side, *n* (%)	
Right	14 (44)
Left	18 (56)
Preoperative renal pelvis diameter (mm)	34 (27–45)
Preoperative imaging, *n* (%)	
MAG3 renal scan	25 (78)
Uro-MRI	7 (22)
Differential renal function <45%, *n* (%)	10 (31)
Aberrant crossing vessel, *n* (%)	12 (38)

MAG-3 = technetium Tc 99m mercaptoacetyltriglycine-3; R-RALP = retroperitoneal robot-assisted laparoscopic pyeloplasty; Uro-MRI = uro–magnetic resonance imaging with functional evaluation.

Table 3 – Surgical variables of the study cohort

	R–RALP (*n* = 32)
Stent, *n* (%)	
One blind-ending JJ stent	6 (19)
Black-Star magnetic stent	25 (78)
External pyeloureteric stent	1 (3)
Perirenal drainage, *n*	0
Set-up time (min)	32 (24–43)
Anastomosis time (min)	62 (51–76)
Console time (min)	137 (108–167)
Conversion, *n*	0
Postoperative renal pelvis diameter (mm)	14 (5.7–26.5)
Complications (Clavien-Dindo), *n* (%)	
I, II	3 (9)
IIIa, IIIb	1 (3)
Redo pyeloplasty, *n*	0

R-RALP = retroperitoneal robot-assisted laparoscopic pyeloplasty.

vis diameter: 34 mm, median postoperative renal pelvis diameter: 14 mm).

No family felt pressured to be discharged from hospital. All parents except two were satisfied with the DS care pathway. Two parents would have preferred to stay overnight to be more secure.

4. Discussion

Our bicentric study is the first to prospectively evaluate DS in selected children undergoing R-RALP. As well as establishing clear surgical criteria for inclusion, the current study demonstrates feasibility, safety, and good short-term results. We attribute the success of this protocol to the establishment of a dedicated multidisciplinary team to guarantee adequate family support and contingency plans to ensure safety netting. Overall, parental satisfaction was excellent thanks to thorough counselling, the complication rate was low, and surgical outcomes were of high standard.

In general, DS rates have increased steadily over the past 25 yr, with wide-ranging advantages to patients (eg, minimal disruption, faster recovery, and increased satisfaction), hospitals (eg, greater theatre utilisation, bed utilisation, reduced waiting lists, etc.), and health systems (eg, cost efficiency) [9,23]. DS represents a natural extension of the minimally invasive revolution, of which robotic surgery is the most recent iteration.

Several principles and considerations must be upheld. Patient safety remains the cornerstone of the programme. Patient selection must be judicious, and strict inclusion criteria should be developed and regularly reviewed. Thus, standard and objective intraoperative and discharge criteria for DS surgery should be developed and implemented. Immediate access to the operating surgeon and meticulous follow-up are imperative to facilitate expedient management of postoperative complications [24].

In adult urology, increasingly complex procedures are being reported as day procedures [25,26]. There are many factors at play that shape these decisions, including culture, expectations, availability of appropriate facilities and support staff, and funding. Indeed, the length of stay following any procedure remains strongly dependent on the health care system. In recent years, reconstructive paediatric urological procedures have been piloted as day procedures. As early as 2004, Mohamed et al [27] reported in a retrospective study the success of implementing a DS admission policy for pyeloplasty in paediatric cases. Impressively, 85% of their 209 pyeloplasty patients (mean age 2.5 yr) over 4 yr were discharged the same day, with no reported readmissions during the immediate or delayed follow-up period. Open unilateral extravesical ureteric reimplantation has been reported as DS in a large cohort of children (n = 250) [28]. No urethral catheter or drain was a criterion for establishing this pathway, and performing this procedure as DS represented a shift in the therapeutic paradigm.

MIS has revolutionised paediatric urology, and robotic surgery has enhanced this further with increased dexterity, superior optics, improved ergonomics, and greater precision [29]. These factors translate to decreased operative time when compared with conventional laparoscopic pyeloplasty [18,19]. The reported success rates of robotic pyeloplasty in children are comparable with those of open surgery [18,30,31]. Additionally, length of hospital stay and use of opioid analgesics are reduced in RALP compared with those in open surgery [30], laparoscopy [19], or both [18]. A synthesis of these data places RALP as the likely procedure of the future, and the possibility of performing this in a DS setting makes it even more appealing.

The Children's Hospital of Philadelphia has recently published their experience performing transperitoneal RALP as DS in 13 children [32]. The mean length of surgery (skin to skin) was 71 min (range 47–92 min). Patients were in PACU for a mean duration of 1.2 h (range 1–2 h) and remained in the stepdown area until discharge. All children were discharged home within 12 h following the completion of surgery. Children had their urethral catheter removed once tolerating oral intake postoperatively, and all patients passed the trial of void prior to discharge. The ureteric stent was removed 2 wk postoperatively. There were no subsequent ER visits or readmissions. The Cincinnati Children's Hospital reported transperitoneal RALP as DS in 17 children, with a tubeless technique (no internal or external ureteral stents, drains, or urethral catheters) [33]. No 30-d complications, ER visits, or readmissions were observed.

Neheman et al [34] described the perioperative outcomes, 30-d complication rate, ER visits, and readmissions in a cohort of 135 children who underwent DS following robotic surgery over a 7-yr period. In their cohort, most children underwent pyeloplasty (n = 62) or extravesical ureteric reimplantation (n = 55). The procedures were performed without drains or urethral catheters, and ureteric stents were utilised in a minority of cases. During the study period, 20 children were excluded due to family reservations regarding same-day discharge. During the 30-d follow-up period, there were nine complications (6.7%), of which only one (0.7%) was of high grade (Clavien-Dindo III). There were nine ER visits (6.7%) including five readmissions (3.7%). Their study provides a further basis that DS robotic surgery in paediatric urology can be performed safely. However, generalisability is limited by the performance of surgery by only two senior surgeons over 7 yr.

As the aim of the current study was to evaluate the feasibility and safety of performing R-RALP as DS, we included only short-term follow-up of this cohort. However, long-term outcomes will subsequently be reported with time. Cost effectiveness is an important consideration when establishing a paediatric robotic programme. Although initial costs may be daunting, cost effectiveness is a moving target as the market continues to develop. We plan a prospective study to specifically address this question, particularly including the advent of the current DS programme [35]. Nevertheless, these initial results in select patients within a dedicated care team and designated pathway are encouraging. With financial costs assuming increasing importance, minimising hospital stay will result in reduced treatment and hospital costs. Further studies are necessary to evaluate cost effectiveness and to determine whether this success can be achieved routinely in a broader context.

5. Conclusions

This study supports the feasibility and safety of R-RALP as DS in children. Care must be taken when establishing a care pathway that strict criteria are developed, followed, and reviewed regularly. By establishing a dedicated multidisciplinary team, high level of parental satisfaction was achieved. Implementation of such programmes may help minimise postoperative interventions, allow faster recovery and return to activities, and diminish the risks of exposure that exist in an inpatient setting. This approach has now become our new institutional standard, with the goal of improving the quality of care that we deliver to children and families. Cost-effectiveness analyses are required to further elaborate the benefits of this approach.

***Author contributions*:** Thomas Blanc had full access to all the data in the study and takes responsibility for the integrity of the data and the accuracy of the data analysis.

Study concept and design: Blanc, Paye-Jaouen.
Acquisition of data: Broch, Bruneau, Glenisson, Botto, Goulin, Lopez, Querciagrossa.
Analysis and interpretation of data: Blanc, Broch, Paye-Jaouen.
Drafting of the manuscript: Broch, Blanc.
Critical revision of the manuscript for important intellectual content: El Ghoneimi, Dahmani, Taghavi.
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***Data sharing*:** Data are not available to other researchers. The procedures carried out with the French data privacy authority (CNIL, Commission nationale de l'informatique et des libertés) do not provide for transmission of the database or the information and consent documents signed by the patients. Consultation by the editorial board or interested researchers may nevertheless be considered, subject to prior determination of the terms and conditions of such consultation and in respect for compliance with the applicable regulations.

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