ORIGINAL ARTICLE

Efficacy of a fast-track pathway for managing uncomplicated renal or ureteral colic in a hospital emergency department: the STONE randomized clinical trial of Sonography and Testing of a Nephrolithiasis Episode

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Objectives. To evaluate a fast-track pathway utilizing point-of-care (POC) testing and sonography as soon as uncomplicated renal or ureteral colic is suspected and to compare the POC clinical pathway to a standard one.

Methods. Unblinded randomized controlled clinical trial in a hospital emergency department (ED). We enrolled patients with suspected uncomplicated renal or ureteral colic and randomized them to a POC or standard pathway (1:1 ratio). Duration of ED stay, treatments, the proportion of diagnoses other than uncomplicated colic, and 30-day complications were analyzed.

Results. One hundred forty patients were recruited between November 2018 and October 2019; data for 124 were analyzed. The mean (SD) total time in the ED was 112 (45) minutes in the POC arm and 244 (102) in the standard arm ($P < .001$). Treatments, alternative diagnoses, and complication rates did not differ.

Conclusion. The use of a fast-track POC pathway to manage uncomplicated colic in the ED is effective and safe. It also reduces the amount of time spent in the ED.

Keywords: Colic, renal or ureteral. Point-of-care ultrasound. Point-of-care testing.

Eficacia de una vía de alta resolución en la evaluación del cólico renoureteral no complicado en un servicio de urgencias hospitalario: un ensayo clínico aleatorizado (Estudio STONE)

Objetivo. Evaluar una vía de alta resolución (vía POC) que utiliza análisis en el punto de atención (*point-of-care testing* –POCT–) y ecografía en el punto de atención (*point-of-care ultrasonography* –POCUS–) en la sospecha del cólico renoureteral (CRU) no complicado y compararla con la vía estándar (vía STD).

Método. Ensayo clínico aleatorizado, controlado, no ciego, realizado en un servicio de urgencias hospitalario (SUH). Incluyó pacientes con sospecha clínica de CRU agudo y se aleatorizaron 1:1 a seguir vía POC o vía STD. Se analizó el tiempo de estancia en el SUH, el tratamiento administrado, la proporción de diagnósticos alternativos a CRU y las complicaciones a 30 días.

Resultados. Entre noviembre de 2018 y octubre de 2019, se reclutaron 140 pacientes de los que se analizaron 124. El tiempo de estancia total en el SUH de la vía POC fue de 112 minutos (DE 45) y en la vía STD 244 minutos (DE 102) ($p < 0,001$). No hubo diferencias en el tratamiento administrado en urgencias, en el número de diagnósticos alternativos, ni en las complicaciones a 30 días.

Conclusiones. La utilización de una vía de alta resolución del manejo del CRU en un SUH es eficaz, segura y reduce el tiempo de estancia en urgencias.

Palabras clave: Cólico renoureteral. Ecografía en el punto de atención. Pruebas de laboratorio en el punto de atención.

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All authors have confirmed their authorship in the author responsibilities document, publication agreement, and assignment of rights to EMERGENCIAS.

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Article information:
Received: 22-3-2020
Accepted: 31-5-2020
Online: 20-10-2020

Editor in charge:
Aitor Alquézar Arbé

Introduction

Hospital emergency departments (EDs) have to manage medical care times and waiting saturation appropriately, as these factors are related to quality of care and patient safety[1]. A significant part of the waiting time relies on the delay in laboratory results, which are a marker of quality management[2]. There are devices that allow blood tests to be performed at the point of patient care -PointOfCare Testing (POCT) - rather than in the main laboratory. The implementation of these analyzers in the ED can facilitate diagnosis and earlier decision making[3,4]. POCT analyzers allow blood gases to be measured and other parameters such as hemoglobin, hematocrit, creatinine, electrolytes and lactic acid to be measured[5]. Previous studies have reported the use of POCT analyzers positively[5,6]. However, more studies focused on the evaluation of specific diseases are needed[7,8].

Acute renoureteral colic (RUC) is one of the most frequent reasons for consultation in the ED. Typically, it

presents as low back or groin pain. At least 16% of males and 8% of females will experience RUC at some point in their lives[9]. However, there are other diseases that may have a similar clinical presentation to RUC such as pyelonephritis, ectopic pregnancy, ovarian torsion, dysmenorrhea, abdominal aortic aneurysm, intestinal obstruction and other intestinal inflammatory processes[10].

The usual management of patients with a first episode of suspected RUC is analgesia and hydration, unless other diseases are suspected or good control of pain is not achieved[10,11]. Imaging is recommended in these cases. Point-of-care ultrasound (PointOfCare UltraSonography -POCUS-), performed by the ED physician himself, is a fast, safe, cost-effective and accurate technique and is therefore useful in the differential diagnosis of RUC[12]. In our setting, ultrasound is the imaging test of choice: sometimes it allows direct visualization of the presence of calculi and in most cases indirect signs (unilateral hydronephrosis) of lithiasis are observed[13,14]. Although computed tomography (CT) has an overall accuracy of 98%[12], it involves exposure to radiation and longer waiting times for its performance. On the other hand, it has been suggested that clinical presentation is sufficient to diagnose RUC and, in cases of uncomplicated RUC, emergency radiological testing does not reduce morbidity compared to after 23 weeks[15].

We therefore hypothesized that a high-resolution pathway in the management of uncomplicated RUC with combined use of POCT and POCUS (POCUS pathway) could be feasible and effective compared to the standard of care pathway (STD pathway). The primary objective was to analyze ED length of stay. Secondary objectives were to analyze the treatment administered, the proportion of alternative diagnoses to RUC and complications at 30 days.

Method

This is a randomized, controlled clinical trial that compared a high-resolution pathway -via POC- with care via STD. The study was conducted at the Hospital de la Paz (Madrid) which is an urban, tertiary, university hospital, providing care to a reference population of 527,366 inhabitants, has 1,308 beds and treats 285,108 emergencies per year. The recruitment period was 12 months, from November 2018 to October 2019. Patients attending the ED for symptoms suggestive of uncomplicated RUC, with symptom onset within 24 hours prior to consultation and a score ≥ 4 on the visual analogue pain scale were included. Patients with hemodynamic instability, temperature ≥ 37.2°C, polytraumatized, patients with a diagnosis of renal colic in the previous month, those under 18 years of age, pregnant women, and those who did not sign the informed consent were excluded. Follow-up was performed during their hospital stay and at 1 month after inclusion. Patients were randomized 1:1 to the POC or the STD route. Due to its characteristics, the study was not blinded.

All patients on the STD pathway underwent blood analysis with complete blood count, glucose, electrolytes, renal function and coagulation, and urinalysis in a central laboratory analyzer. Urine culture and abdominal radiography were performed at the discretion of the attending physician. In the POC pathway (Figure 1), the STONE (Sonography and Testing Of a Nephrolithiasis Episode) protocol was performed on all patients. This algorithm was developed in the context of the present study and consisted of performing a POCUS examination and POCT analysis on all patients with suspected RUC. POCT analysis was performed with the ABL90 FLEX Plus analyzer (Radiometer®, Denmark) which determines creatinine, urea, pH, pO_2, pCO_2, pCO_2, HCO_3, chlorine, sodium, potassium, calcium, hemoglobin and lactic acid. In case of moderate hydronephrosis or a high POCT creatinine value, a central laboratory test and an abdominal CT scan without contrast were performed. Patients with altered creatinine values or inadequate pain control were excluded from the analysis. The ultrasound study was performed by a POCUS expert emergency physician who met the criteria of the American College of Emergency Physicians[16]. The ultrasound followed the FAST (Focused Abdominal Sonography for Trauma) protocol to evaluate the presence of intraperitoneal free fluid[17] and also looked for signs of hydronephrosis. Hydronephrosis was classified on a scale of 4 categories: absent, mild, moderate and severe. At the suprapubic level, the bladder volume was estimated in milliliters (width x depth x height x 0.7)[18]. The abdominal aorta was visualized to rule out the presence of aneurysm (diameter ≥ 3 cm)[19]. The ultrasound study required less than 10 minutes for each patient. The scans were performed with a GE VENUE ultrasound scanner with convex transducer (1.54.5 MHz) (General Electrics® Healthcare, Chicago, IL, USA).

The following data were collected from each patient: demographic data (age and sex), comorbidities (previous RUC, concomitant urological disease, cardiovascular disease), symptoms of the current episode (renal fossa pain, hematuria, nausea or vomiting, time of evolution), physical examination (visual analogue pain scale, blood pressure, heart rate and oxygen saturation), analytical parameters (sodium, potassium, creatinine and urea), analgesic treatment administered, and ultrasound findings on POCUS. Adverse events in the ED (proportion of alternative diagnoses to RUC, renal fornix rupture or catheter insertion) were collected. All patients were followed up at 30 days by medical record review. Complications at 30 days were defined as any readmission, acute renal failure or hospitalization during follow-up. The primary outcome variable was the length of stay in the ED, from ED arrival to discharge. For this purpose, the time of arrival at the ED, triage, first medical contact, first nursing contact, time of validation of analytical results, time to pain control and discharge from the ED were recorded. Secondary outcome variables were considered to be the analgesia administered, the proportion of patients with an alternative diagnosis to RUC and complications during follow-up.

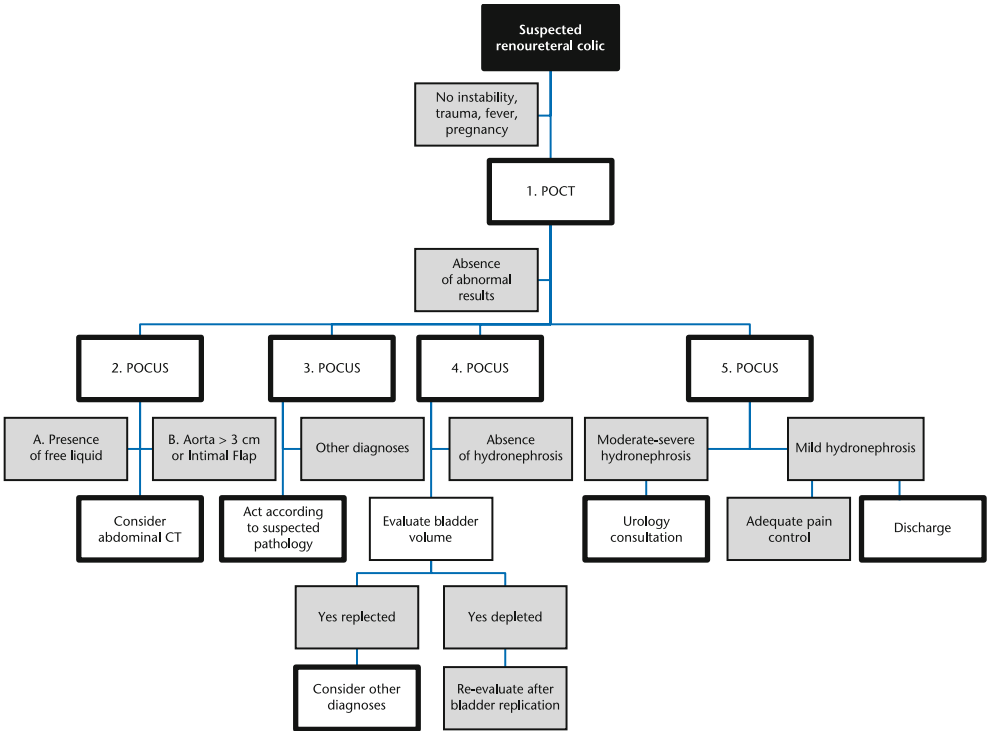

Figure 1. STONE (Sonography and Testing Of a Nephrolithiasis Episode) protocol for patients with a suspected acute renoureteral colic episode.
POCT: point-of-care laboratory tests; POCUS: point-of-care ultrasound; CT: computed tomography.

The sample size was calculated in relation to the main objective, with an error of 5%, a confidence level of 95%, and a power of 80%. A 1-hour difference in ED length of stay between the 2 pathways studied was considered clinically significant. With these assumptions, the estimated sample size was 128 patients, 64 in each group. Qualitative variables were expressed as absolute value and percentage, quantitative variables as mean and standard deviation (SD). For comparisons between groups, the chi-square test or Fisher's exact test was used for qualitative variables and Student's t-test for quantitative variables. Statistical significance was established at p value < 0.05. Statistical analyses were performed with IBM SPSS v20.0 software (SPSS Inc., Chicago, IL, USA).

The study was conducted in accordance with the Declaration of Helsinki and was approved by the Clinical Research Ethics Committee (IRB Number: HULP5121). Written informed consent was obtained from each patient enrolled. The study was registered with the U.S. National Institutes of Health. (ClinicalTrials.gov) # NCT03706404 and in the European Union Medicines Regulatory Authorities Clinical Trials Database (EudraCT) ID 2018-001670-14.

Results

Between November 2018 and October 2019, 140 patients were included, 70 in each study group (Figure 2). We excluded from the analyses 6 patients in the POC pathway, 4 for creatinine ≥ 1.5 mg/dL and 2 for poor pain control, and 6 patients in the STD pathway, 5 for creatinine ≥ 1.5 mg/dL and 1 for poor pain control. Finally, 128 patients were analyzed, 64 in each group. The final diagnosis was RUC in 124 patients. The baseline characteristics of the included patients are shown in Table 1: 77 patients (60.2%) were women and the mean age was 44 years (SD 15). In 111 patients (86.7%) it was the first episode of RUC. There were no differences in baseline characteristics, except for pain assessment which was 8 (SD 1.3) in the STD pathway and 8.5 (SD 1.6) in the POC pathway (p = 0.034).

There were no differences in the 2 groups in the times from arrival at the emergency department to triage or in the time from triage to first medical contact (Table 2). The POC pathway had shorter times (p < 0.005) from first medical contact to nurse care, from nurse care to pain control, to validation of laboratory tests, and to ED discharge, and in time from pain control to ED discharge. The total ED length of stay for the POC pathway was 112 (SD 45) and for the STD pathway 244 (SD 102) (p < 0.001).

In the POC approach, POCUS showed mild hydronephrosis in 57 patients (89%), moderate hydronephrosis in 3 (4.7%) and no hydronephrosis in 4 cases (6.3%). In addition, POCUS allowed early diagnosis in one case of ruptured abdominal aortic aneurysm, another case of uncomplicated diverticulitis and in 2 pa-

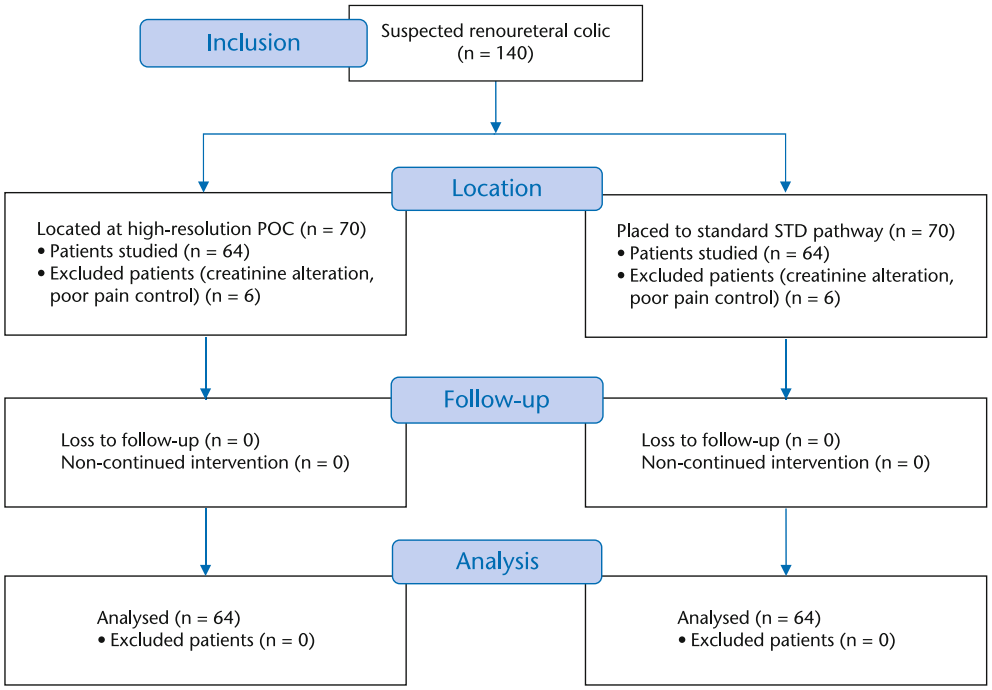

Figure 2. Patient inclusion flowchart.
POCT: point-of-care laboratory tests; POCUS: point-of-care ultrasound.

tients free fluid was observed in the context of complicated RUC.

Table 1. Demographic and clinical characteristics of the included patients

	TOTAL N = 128 n (%)	POC N = 64 n (%)	STD N = 64 n (%)	p
Sex (female)	77 (60.2)	42 (65.6)	35 (54.7)	0.206
Age (years) [mean (SD)]	45 (15)	44 (15)	45 (15)	0.458
History		N (%)		
Previous renal colic	17 (13.3)	7 (10.9)	10 (15.6)	0.435
Cardiovascular disease	13 (18)	11 (17.2)	12 (18.8)	0.818
Urologic disease	7 (5.5)	6 (9.4)	1 (1.6)	0.52
Symptoms				
Pain in left renal fossa	44 (34.4)	18 (28.1)	26 (40.6)	0.137
Right renal fossa pain	84 (65.6)	46 (71.9)	38 (59.4)	0.137
Nausea or vomiting	12 (9.4)	7 (10.9)	5 (7.8)	0.544
Hematuria	4 (3.1)	2 (3.1)	2 (3.1)	1.000
VAS	8.3 (1.4)	8 (1.3)	8.5 (1.6)	0.034
Symptom onset > 12 hours	29 (22.7)	9 (14.1)	20 (31.2)	0.20
Physical examination [mean (SD)]				
SBP (mmHg)	129 (21)	128 (23)	129 (17)	0.060
DBP (mmHg)	78 (78)	78 (13)	77 (11)	0.430
Heart rate (bpm)	78 (16)	79 (16)	78 (17)	0.786
Temperature (ºC)	35.9 (0.6)	35.7 (0.6)	36.0 (0.5)	0.372
SO_2 (%)	98.1 (1.4)	98.1 (1.5)	98.0 (1.2)	0.207
Analytical [mean (SD)				
Sodium (mEq/L)	140 (3.1)	140 (3.6)	140 (2.3)	0.206
Potassium (mEq/L)	3.9 (0.3)	3.9 (0.3)	3.9 (0.3)	0.186
Creatinine (mg/dL)	0.9 (0.2)	0.8 (0.2)	1.0 (0.3)	0.054
Urea (mg/dL)	34 (11)	31 (10)	37 (12)	0.185

SD: standard deviation; VAS: visual analog pain scale; NA: not applicable; POC: point-of-care - high-resolution pathway; SO_2: oxygen saturation; STD: standard pathway; DBP: diastolic blood pressure; SBP: systolic blood pressure.

There were no differences in treatments administered in the ED, neither in the evaluation of pain at discharge nor in the follow-up of events at 30 days. There was one patient who reconsulted and hydronephrosis was found, which was not present in the first evaluation in which the bladder was not well repleted. Between 11 and 15% of patients with ureter stones may have no or less hydronephrosis, depending on the patient's hydration[20].

Discussion

The main finding of the study is the reduction in the time spent in the ED in the POC approach compared to the STD approach, with no differences in follow-up. Consequently, we consider the POC approach to be a safe and effective alternative for the management of uncomplicated RUC.

Patients with uncomplicated RUC in our study were young, with low comorbidity, good therapeutic response and a low rate of complications during follow-up. These results are similar to those reported in the literature[10,11]. Our findings are similar to those obtained in the study by Smith-Bindman et al.[12], which showed that the length of stay in the emergency department was shorter in the POCUS group compared to CT or ultrasound by radiology (5.1 vs. 6.2 and 6.4 hours, respectively). A previous study obtained results comparable to those of our study, with a reduction in ED length of stay of 32%[20]. In that study, with a population similar to ours, POCUS was used to detect hydronephrosis and accelerate the indication for abdominal

Table 2. Comparison of outcome variables between the POC and STD groups

Result variables	TOTAL N = 128 n (%)	POC N = 64 n (%)	STD N = 64 n (%)	p
Mean time (min) [mean (SD)]				
From ED arrival to triage	11.2 (9.7)	10.9 (10.6)	11.4 (8.7)	0.766
From triage to first medical contact	27.1 (30.1)	21.9 (20.8)	32.2 (36.6)	0.055
From first medical contact to nursing care	24.8 (26.1)	17.03 (12.5)	32.7 (33.2)	0.001
From first medical contact to POCUS	48.2 (28.3)	48.2 (28.3)	NA	–
From nursing care to lab test validation	47.8 (46.9)	11.4 (14.7)	84.1 (39.4)	< 0.001
From nursing care to pain management	52.5 (57.2)	34.3 (29.0)	70.8 (71.3)	< 0.001
From nursing care to discharge	115.9 (94.9)	61.0 (38.3)	168.2 (103.1)	< 0.001
From pain management to discharge	62.9 (70.4)	26.7 (28.5)	97.4 (80.7)	< 0.001
Total ED length of stay	179.7 (103.5)	111.9 (45.5)	244.3 (102.2)	< 0.001
Treatment administered				
Nonsteroidal anti-inflammatory drugs	91 (71.1)	49 (76.6)	42 (97.7)	0.172
Tramadol	29 (22.7)	13 (20.3)	16 (25)	0.526
Morphine	3 (2.3)	1 (1.6)	2 (3.1)	0.559
Paracetamol	29 (22.7)	11 (17.2)	18 (28.1)	0.139
Metamizole	52 (40.6)	22 (34.4)	30 (46.8)	0.150
Metoclopramide	34 (26.6)	15 (23.4)	19 (29.7)	0.423
Events during the study	5 (7.8)	5 (7.8)	1 (1.5)	0.208
Proportion of alternative diagnoses to RUC	4 (6.3)	3 (4.7)	1 (1.5)	0.619
Urinary tract infection	2	1	1	1.000
Abdominal aortic aneurysm	1	1	0	1.000
Diverticulitis	1	1	0	1.000
Renal fornix rupture	1	1	0	1.000
Double J catheter insertion	1	1	0	1.000
After discharge				
VAS (SD)	1.76 (1.2)	1.76 (0.98)	1.77 (1.4)	0.895
Adverse events during follow-up	17 (13.3)	9 (14.1)	8 (12.5)	0.795
Pain exacerbation	13 (10.1)	6 (9.4)	7 (10.1)	0.770
Urinary tract infection	3 (2.3)	2 (3.1)	1 (1.6)	0.559
Double J catheter insertion	1 (0.8)	1 (1.6)	0	1.000

RUC: renoureteral colic; SD: standard deviation; VAS: visual analog scale for pain; min: minutes; POC: point-of-care - high-resolution pathway; POCUS: point-of-care ultrasound; STD: standard pathway; ED: hospital emergency department; SBP: systolic blood pressure.

CT, avoiding the waiting time for laboratory results. Although the performance of abdominal CT is not common in our setting, it is noteworthy that the mean time from arrival at the ED to the performance of CT was only 39 minutes. Another previous study[21] compared the reduction in the performance of CT when a strategy based on the performance of POCUS was followed versus the standard one. Although no difference in waiting time was observed, this finding was attributed to the lack of strength of the study.

In contrast to these previous studies[12,20,21] in our study, waiting times were recorded in different time periods. The difference in the time from the first medical contact to the nursing contact and from the administration of medication to pain control is noteworthy. This result could be due to the fact that the presence of the investigator who recruited the patient would have served to expedite patient care. Another explanation is that we did not take into account factors such as ED overcrowding, which could have prolonged the waiting time. The remaining times, as expected, were lower in the POC group.

Pain control is one of the main factors conditioning discharge from the ED, but we observed that in the STD group, the mean validation time of the analytical tests was greater than that of pain control. We also consider that having a confirmed diagnosis of uncomplicated RUC could facilitate discharge, avoiding a waiting time aimed at observing the evolution.

Regarding the analgesic treatment administered, no significant differences were observed. It was based on nonsteroidal anti-inflammatory drugs followed by tramadol[10,11]. In general, these 2 treatments were maintained at ED discharge.

The use of a strategy based on POCUS has been proven to be safe and does not lead to a delay in the diagnosis of other pathologies when compared to other diagnostic strategies[12]. Although, in our study, we did not observe significant differences in the proportion of alternative diagnoses and adverse events at follow-up, it is to be expected that in routine practice, the performance of POCUS would allow earlier detection of possible complications. A meta-analysis observed that ultrasound performed by radiologists can have a sensitivity of 70-76.5% and specificity of 94.4-100%, being comparable to that performed by the ED physician, with an interobserver reliability index of 87.5%[22]. In line with the above, we consider that POCUS should be performed as a first-line imaging test. Therefore, we propose the application of an algorithm (STONE) to assess RUC in the ED, which could guide the evaluation and management of these patients (Figure 2), facilitating

the incorporation of both tools at the point of care (POCT and POCUS), in 5 simple steps. POCUS can be a very powerful tool for detecting complications or guiding maneuvers, provided it is performed systematically, as has been seen in other pathologies[23]. The external validity of this protocol should be tested in future studies.

This is the first study to evaluate the impact of using a POC protocol to better and more rapidly stratify patients with an uncomplicated RUC episode for early discharge. It should be noted that complicated patients (hemodynamically unstable, abnormal renal function, fever or polytraumatized) were excluded. In the protocolized application of this high-resolution pathway, if POCT is used to identify mild hydronephrosis (without impaired renal function), discharge can occur more than 1 hour earlier. In addition, by adding the POCUS protocol, the possibility of more severe disease that could be mistaken for RUC can be safely excluded. Therefore, following the proposed protocol could shorten ED lengths of stay without increasing adverse events.

This study has several limitations. First, ED saturation factors that could have prolonged waiting times were not considered, although the randomization process minimizes this confounding factor. Second, because of the study design, the study could not be blinded to either the patient or the investigator. Third, in the STD pathway, analytical analysis was performed in all cases. This fact could explain part of the delay in the STD approach. In routine clinical practice, laboratory tests are not always performed when RUC is suspected. Fourthly, recruitment was not consecutive, but depended on the availability of the investigators (during their working hours). Fifth, the application of the proposed protocol requires the availability of a suitable ultrasound scanner and POCT analyzer. Finally, POCUS is an operator-dependent technique. In the case of this study it was performed by an emergency physician expert in this technique, which may have favored the POC approach, although previous studies have shown that urinary tract POCUS can be performed and interpreted accurately by emergency physicians[12,21,22].

In conclusion, the use of a high-resolution pathway in the management of RUC that combines the use of POCT and POCUS is effective in the management of RUC in the ED and reduces the length of stay in the ED, with no significant differences in 30-day follow-up. There were no differences in the treatment administered in the ED, in the number of alternative diagnoses, or complications at 30 days.

Conflicting interest: The authors declare no conflict of interest in the conduct of this study.

Financing: The authors declare the non-existence of funding in relation to this article.

Ethical responsibilities: All authors have confirmed the maintenance of confidentiality and respect for patients' rights in the author's responsibilities document, publication agreement and assignment of rights to EMERGENCIAS. The study was conducted in accordance with the Declaration of Helsinki and was approved by the Clinical Research Ethics Committee. Written informed consent was obtained from each patient enrolled (IRB Number: HULP5121). The study was registered with the U.S. National Institutes of Health (ClinicalTrials.gov). (ClinicalTrials.gov) # NCT03706404 and in the European Union Drug Regulatory Authorities Clinical Trials Database (EudraCT) ID 201800167014.

Article not commissioned by the Editorial Board and externally peer-reviewed.

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