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Original Article

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Litigation in the management of urinary stone disease

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Objective

To present common technical and non-technical issues leading to medicolegal litigation, illustrated by a series of 54 cases, with the aim of using these examples to prevent harm to patients and to prevent surgeons from having to experience the stress of litigation.

Methods

A series of 78 medicolegal litigation cases reviewed by a single expert witness over 13 years from 2008 to 2021 was analysed by two reviewers. Twenty-nine cases were identified as having a non-technical learning point and 25 were identified as having a technical learning point. These are discussed using illustrative examples and the steps that could have avoided these issues are considered.

Results

All major issues and themes are illustrated with cases demonstrating the errors that lead to litigation and the often-simple steps that can be taken to avoid them. Out of 29 non-technical issues, 13 involved consent issues (45%), eight involved delays in treatment (28%) and eight involved failure to provide adequate safeguarding advice (28%). Out of 25 technical issues, 13 cases involved intra-operative problems (52%) including nine ureteric injuries, eight involved errors or omissions in the immediate preoperative period (32%) and four resulted from decisions around emergency decompression of the obstructed infected kidney. These emergency cases featured complications of amputation (two out of four) and death (one out of four). These decisions are complex and there are many subtleties to these cases, which are discussed in detail.

Conclusion

We hope that this case series highlights the potentially catastrophic outcomes of even small errors of judgement, and allows careful stone surgeons to learn from the experiences of those unfortunate others without having to encounter these situations themselves.

Keywords

medicolegal, litigation, safety, consent, obstructed infected kidney, #KidneyStones, #EndoUrology, #UroStone, #UroUTI

Introduction

'Experience keeps a dear school, but fools will learn in no other' Benjamin Franklin.

Claims against urologists have steadily increased over the years, with total claims increasing sevenfold from 1997 to 2017 [1]. The factors contributing to this include an increased number of urologists performing an increased volume of surgery, but nevertheless the risk of an individual surgeon being sued has increased 1.5-fold to 0.28 cases per year in 2019 [2]. In other words, a urologist can expect about nine claims against them over the course of a 30-year career. And yet this is just the tip of the iceberg, as it is thought that only 2% of adverse events due to negligence actually result in claims [3]. It is a sobering thought that by this calculation, the average urologist might be making 14 potentially negligent mistakes a year and getting away with most of them.

In 2011, stone-related procedures were the most common area for litigation in urology in the UK [4]. An analysis from the USA concluded that over half of claims were a result of technical issues such as improper performance of a procedure and from diagnostic errors [5]. This still leaves a substantial minority of cases arising from non-technical issues.

We discuss factors that can lead to litigation in the management of urinary tract stone disease in a series of 54 cases derived from medicolegal litigation cases. Some of these are rare situations and others will sound like perfect storms of misfortune, but nevertheless these are cases that really

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happened. Our aim in sharing the stories of these cases is to prevent harm to patients and to prevent surgeons from having to experience the stress of litigation.

Materials and Methods

Seventy-eight medicolegal litigation cases reviewed by a single expert witness (J.R.) over a 13-year period from 2008 to 2021 were analysed by two reviewers (B.Y. and L.G.). Twenty-nine of the 78 cases identified a non-technical learning point, and 25 cases identified a technical learning point. The cases were categorized by theme as shown in Fig. 1.

Each theme is illustrated with examples from cases, and we also present a discussion of the safeguards at a systemic and individual level that could have prevented or mitigated the errors that led to litigation.

We do not discuss the outcome from such cases, the size of the settlement or the legal costs. While such information would be interesting, we believe what matters most is to avoid the process of litigation in the first place.

Results

Non-technical: Consent Issues

Consent issues are the low hanging fruit of litigation prevention and yet, despite the publicity surrounding the fallout from poor consent practice, they remain a potent source of litigation. Thirteen out of 29 non-technical cases feature alleged inadequate consent following a complication from stone management. Of these, eight allege failure to discuss a complication, three allege that their options were not presented adequately and two allege failure to explain the material effects of the complications. While all complications sustained are rare, they are all well recognized and detailed in the BAUS patient information leaflets [6,7].

Complication Not Consented for

Eight of the 13 consent-related cases feature recognized complications with no evidence of discussion during the consent process.

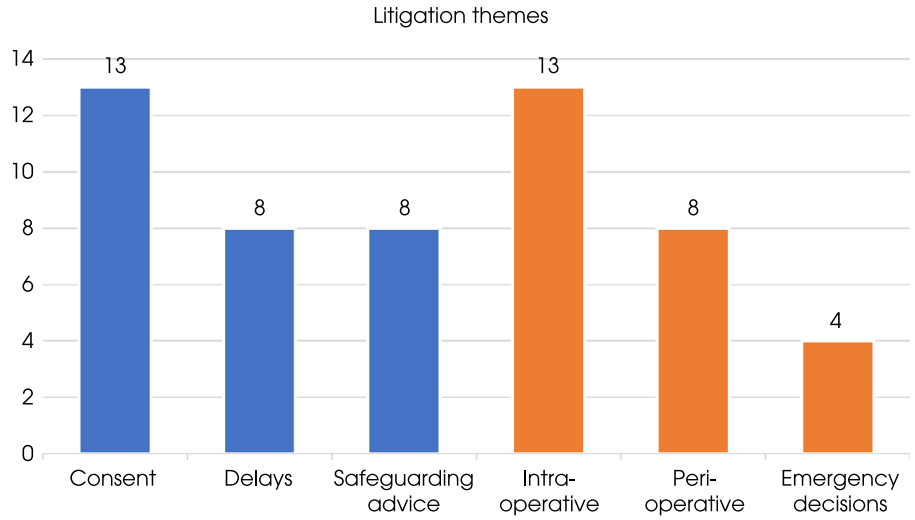
Three cases involved percutaneous nephrolithotomy (PCNL): one case involved a patient who sustained a haemothorax requiring chest drain insertion and two involved bowel perforations during access, necessitating right hemicolectomy in both cases.

Five cases involved ureteroscopy: one case resulted in ureteric stricture formation subsequently requiring nephrectomy, and four involved ureteric injuries including one ureteric avulsion.

Case 1 was the ureteric avulsion case. The consenting doctor on the day of surgery was a core surgical trainee with limited urological experience and no mention of ureteric injury was made on the consent form, nor in the clinic documentation. While this doctor probably should not have been consenting for this procedure, a thorough discussion of the risks in clinic could have formed the basis for a defence; however, as things happened there was no defence to be found.

The lesson here is simple: ensure that all common and/or serious complications are discussed with the patient, and when possible, do so both in clinic and on the day. The BAUS patient information leaflets are a useful guide but 43% of the UK adult population may experience significant difficulty understanding these leaflets [8] and so they should be seen as an adjunct, not a replacement for an explanation. The not-infrequent comment in the notes 'BAUS information

Fig. 1 Themes of litigation cases.



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leaflet provided' may not convince the Court that the surgeon's obligations regarding consent have been fulfilled.

Lack of Equipoise

Three cases arose due to a lack of equipoise when discussing management options with the patient.

Case 2 involved a patient who underwent flexible ureteroscopy (fURS) for an asymptomatic 6-mm renal stone. The fURS was negative and postoperative CT of the kidneys and bladder (CTKUB) did not demonstrate any stone, suggesting that the stone had passed spontaneously prior to surgery. The patient alleged an unnecessary intervention as they were not offered the option of watchful waiting in clinic.

Case 3 involved a patient who underwent PCNL for a 1.6-m renal stone and sustained a bowel injury requiring hemicolectomy. They alleged that, although alternative options were discussed, they were described as inferior to PCNL, which skewed their decision making.

These cases demonstrate the importance of discussing all management options available to the patient, and delivering this discussion with equipoise. Where possible, the benefits and disadvantages of each option should be discussed using objective data such as complications and outcomes rather than subjective opinions such as 'better/worse' as the patient's priorities and views may not align with those of the surgeon!

Material Effects of Complications

Two cases involved a complication that had been mentioned but the effects of the complication were not made clear to the patient.

Case 4 involves a patient who underwent fURS for a 7-mm ureteric stone. They subsequently developed a ureteric stricture requiring nephrectomy. While the risk of 'stricture formation' was documented, the patient had not understood that this could entail major reconstructive surgery or loss of the kidney.

The lesson here is that our obligation as surgeons is not the one-way dispensation of information, but to ensure that the patient fully understands the implications and consequences. There is no place in modern medicine for omitting or downplaying serious complications for fear of putting patients off surgery; on the contrary, it is essential that patients understand, and it is quite right that some might choose not to have surgery as a result.

Non-technical: Delay to Receiving Treatment

Eight out of 29 non-technical cases arose because of perceived delays to the patient's treatment.

Delays

Seven cases involved patients who had ureteric stents inserted in an emergency setting and then alleged long waits for ureteroscopy. Two of these stents were heavily encrusted after 5 months and 10.5 months, respectively. One patient experienced postoperative urosepsis that was alleged to be a result of the 5-month waiting time and one patient experienced stent symptoms for 6 months. The remaining three patients did not experience complications but were nevertheless dissatisfied with the waiting time.

The last case involved a patient who was listed for PCNL for asymptomatic renal stones. Dimercaptosuccinic acid (DMSA) scan at the time of listing demonstrated 43% function on the affected side. After 19 months of waiting, a repeat DMSA demonstrated just 5% function in the kidney, and nephrectomy followed.

Delays in treatment and follow-up are common themes in litigation, but unfortunately these are often out of the control of the surgeon and are expected to become worse in the wake of the COVID-19 pandemic. One thing we can do is to manage patients' expectations around waiting times, and to ensure that discharge summaries do not give unrealistic treatment schedules.

Non-technical: Safeguarding Advice

Eight out of 29 non-technical cases alleged that inadequate safeguarding advice was given.

Four cases involved patients on watchful waiting for small renal stones who experienced stone migration. All of them presented as emergencies and required emergency stenting, with two experiencing infected obstructed kidneys. Three cases involved patients with stone recurrence after fURS who alleged that they were not given stone prevention diet advice. One case involved a patient who was discharged with residual fragments after fURS and re-presented with ureteric stones and an atrophic kidney.

Case 5 involved a patient on watchful waiting for a 4-mm renal stone. Between appointments it migrated to the ureter and he experienced colic and flu-like symptoms at home, but did not connect these symptoms to his stone. When he eventually presented septic as an emergency, he underwent stent insertion and required intensive therapy unit care, with eventual bilateral forefoot amputation. The patient alleged that he was not warned that the stone could migrate, or what he might experience if it did.

Case 6 involved a patient with medullary sponge kidney who was discharged from outpatient clinic after failing to attend several appointments. She re-presented with an acutely obstructing stone but was found to have a non-functioning

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kidney after stenting, and alleged that there was no warning about the possibility of silent obstruction.

Again, the learning points are straightforward. All patients with renal stones should be advised on the possibility of stone migration, the symptoms to look for and the steps they should take. It is also well established that renal stones can recur, and manipulation of diet and fluid intake can reduce this risk [9,10]. Failure to provide such advice is difficult to defend and it is worthwhile to establish departmental procedures to ensure it is universally provided. Care should also be taken when discharging serial non-attenders; the discharge letter should be considered as an opportunity to provide any final safety-netting information.

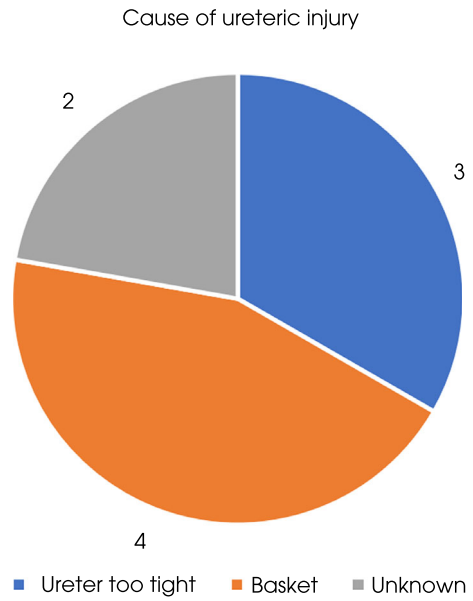
Technical: Intra-operative Issues

Thirteen out of 25 technical issues involved intra-operative problems. These are especially challenging for the surgeon, partly because all surgeons take pride in their technical surgical skills, and partly because the issue almost invariably results from an error or misjudgement on the surgeon's part.

Ureteric Injury

Ureteric injuries and avulsions are some of the most serious complications of ureteroscopy, and this featured in nine of the 13 cases in the intra-operative category. Six of these were ureteric avulsions requiring reimplantation. The other three ureteric injuries resulted in significant strictures, with two eventually requiring nephrectomy. The causes of these ureteric injuries are shown in Fig. 2.

Fig. 2 Causes of ureteric injuries.



Case 7 involved a male patient undergoing primary ureteroscopy for a 5-mm ureteric stone. The ureter was described as 'a little tight' on entry of the ureteroscope. The stone was successfully fragmented with a laser, and it was only on removal of the ureteroscope that the surgeon saw an 8–9-cm segment of ureter stuck to the scope. Subsequent cystoscopy showed a hole in the bladder where this had been avulsed from the ureteric orifice.

Clearly the assessment of resistance to passage of the ureteroscope is subjective. It takes experience to appreciate when a ureter is too tight to safely advance the ureteroscope, and even only 'a little' resistance has the potential to turn into a disastrous ureteric injury. As much as surgeon and patient might wish to treat the stones on the day, the option of inserting a stent and coming back another day is still far preferable to outcomes like these.

Other Intra-operative Issues

The remaining intra-operative issues were as follows.

- Abdominal compartment syndrome from irrigation fluid leaking through a calyceal tear during a mini-PCNL.
- Haemothorax from trans-pleural track placement during PCNL.
- Postoperative sepsis after ureteroscopy in a solitary kidney with no postoperative stent.
- Retained foreign body from a basket disintegrating during fURS.

Technical: Peri-operative Issues

Eight out of 25 technical cases resulted from errors or omissions in the immediate preoperative period. Many of these reflect systemic issues rather than errors by an individual. Nevertheless, the final responsibility lies with the surgeon and these cases highlight the importance of surgeons taking a proactive role in safety checks.

Inadequate Case Review

Three cases involved errors that could have been prevented by the surgeon reviewing the case notes more thoroughly prior to surgery. Two of these involved a failure to identify the correct ureter in a duplex system, and the last was a failure to remove a ureteric stent during a nephrectomy.

Case 8 involved a female patient presenting as an emergency with a 6-mm ureteric stone causing intractable pain. A previous IVU had identified complete duplex systems on both sides. A right ureteric stent was inserted with no comment in the operation note about any duplex system. The patient remained symptomatic after discharge and a

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subsequent X-ray showed the stone to be 'quite separate from the stent'.

Fortunately, this patient was not septic, but the lesson remains that it is good practice to review all recent relevant investigations. Having the relevant images displayed prior to starting a procedure would have provided another opportunity to enhance situational awareness.

Equipment Not Available

Three cases involved the fall-out arising from necessary equipment not being available. In each case the surgeon could have anticipated this equipment being necessary at the time of the WHO briefing at the beginning of the day's operating.

Case 9 involved a male patient with a 2.9-cm stone in a solitary right kidney who underwent elective right PCNL. The nephrolithotomy was successful but, remarkably, no flexible cystoscope was available to inspect the calyces at the end of the procedure. The patient was re-admitted a couple of months later with an obstructing 9-mm right ureteric stone and several calyceal stones despite the recent PCNL. These stones were eventually cleared ureteroscopically, and the expert opinion was that this meant that he could have been rendered stone-free at the time of his PCNL had a flexible cystoscope been available.

A key element in the WHO Surgical Safety checklist is a briefing period at the beginning of the operating list. The surgeon identifies any specific equipment required and the theatre staff confirm its availability [11]. All three cases in our series would have been avoided had this simple check being completed prior to the anaesthetic being administered.

Urine Culture

Two cases involved septicaemia after elective ureteroscopy, with a positive bacterial growth on the preoperative urine culture.

Case 10 involved a male patient awaiting ureteroscopy for an 8-mm ureteric stone with a ureteric stent *in situ*. The preoperative urine culture grew enterococcus faecalis. The surgeon proceeded with ureteroscopy without any attempt to treat this colonization in advance of the procedure, relying on a single prophylactic dose of 160-mg gentamicin at induction of anaesthesia. The patient was discharged without any postoperative antibiotics and somewhat predictably presented with sepsis 3 days later, growing enterococcus on blood culture. He required nearly 2 weeks of hospital treatment. The operating surgeon summed up the lesson in his statement: 'I very much regret not actively looking for the midstream urine culture result prior to surgery [*and acting upon it*]'.

Technical: Emergency Decisions

It is uncontentious that an obstructed infected kidney requires emergency decompression. However, reality is rarely as black and white as that and there can be differing opinions on the details (in which, it is said, the devil lies). How obstructed does 'obstructed' really mean? Is a temperature of 37.5°C enough cause to stent at 02:00 h or can such cases be deferred until the morning? What about 37.6°C, or 37.8°C? Where is the line between the patient who is well and can wait vs the patient in whom a septic storm is brewing?

Four cases involved issues with management of obstructed infected kidneys. One patient died, two required limb amputations and one had sepsis-induced coronary syndrome. The issues in these cases are more subtle and complex and we encourage the reader to consider what they might have done the same or differently.

Case: Time to Theatre

Case 11 involved a female patient with a history of bilateral renal stones. She presented with a few hours of left flank pain, vomiting and sweating. On admission, her pulse rate was 69 min^{-1}, blood pressure 131/52 mmHg, respiratory rate 18 min^{-1}, oxygen saturation 99% and temperature 35.5°C. Blood tests revealed a white cell count of 12.2 x 10^9/L, C-reactive protein of 7 mg/L and raised creatinine of 92 μmol/L. Urine analysis was positive for blood only. She was admitted under urology with a working diagnosis of renal colic, pending a CT scan.

Throughout the night the patient became progressively tachycardic and hypotensive, reaching a pulse rate of 122 min^{-1} and blood pressure of 79/40 mmHg by the morning, although her temperature did not exceed 37.5°C throughout. Sepsis treatment was started with i.v. fluids and gentamicin. The decision was made at approximately 10:35 h to insert a ureteric stent, and CTKUB shortly after confirmed an obstructing 9-mm left distal ureteric stone. Another case was just starting in the emergency theatre and a 3-h delay was anticipated.

As the team were waiting for theatres to free up, it became clear that the patient was not responding to treatment. By 13:30 h her blood pressure had dropped further to 67/46 mmHg, although by this time the window for expediting her surgery had probably been missed. She was eventually anaesthetized at 15:30 h, approximately 5 h after the decision to operate. A stent was inserted and she was transferred to intensive care postoperatively. Despite this she experienced critical lower limb ischaemia, thought to be sepsis-driven, and required bilateral below knee amputation.

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We invite the reader to consider how events might have unfolded had this patient come to their local hospital. Would it have been possible to achieve stent insertion within the 3-h target recommended by the Royal College of Surgeons guidelines [12]? Is this target realistic given the often-competing pressures on the one emergency theatre used by several surgical specialities? The answers are not simple and nor are the deliberations in such cases.

Case: Small Stones

Case 12 involved a female patient presenting with a 1-day history of right flank pain, sweating, diarrhoea and vomiting. On admission, her pulse rate was 120 min^{-1}, blood pressure 69/38 mmHg, respiratory rate 16 min^{-1}, oxygen saturation 98% and temperature 37.1°C. Blood tests showed a white cell count of 20.2 x 10^9/L, C-reactive protein level of 215 mg/L and creatinine of 139 μmol/L, all raised. She was given i.v. fluids and co-amoxiclav, and a CT scan showed mild right hydronephrosis and retroperitoneal inflammation secondary to a 1-mm right distal ureteric stone. The urology cover for this hospital was provided remotely from a nearby hospital, and a telephone referral was made at 14:05 h. The advice given was that it was 'unlikely to require urological intervention' and to continue to manage the patient conservatively.

The patient was reviewed by the general surgery consultant 2 h later, but had not responded to the fluid and antibiotics. Her pulse rate was 76 min^{-1} with a blood pressure of 77/50 mmHg, and her upper extremities were cold with reduced sensation. Urine analysis was negative for nitrites. With evidence of critical ischaemia, a further attempt was made to transfer the patient to urology during the evening. These attempts were frustrated by an unclear transfer pathway for patients requiring intensive care, resulting in a delay overnight as the patient remained critically unwell.

The patient was eventually transferred the following day and stented in the evening, 36 h after presentation. The degree of sepsis-driven peripheral ischaemia eventually necessitated bilateral below knee and upper limb amputations. While the speed with which her condition deteriorated was dramatic and even immediate decompression may still have resulted in some tissue loss, there is no question that the degree would have been less than the devastating amputations that were required.

Again, we invite the reader to consider what might have happened in their department. Was the initial urology opinion (that urological intervention was unlikely to be required) reasonable? For those readers who provide cover to other hospitals, are they confident that their transfer protocols will allow them to deliver the treatment that critically unwell patients require in a timely fashion?

Case: Admission or Discharge

Case 13 involved a female patient presenting with a 3-h history of left flank pain, vomiting and feeling shivery. Her pulse rate was 119 min^{-1}, blood pressure 162/61 mmHg and temperature 36.7°C. Blood tests showed a white cell count of 5.9 x 10^9/L and urine analysis was positive for blood only. She was reviewed in the morning when her pulse rate was 96 min^{-1} and her temperature was 37.2°C, and it was noted that she had 'felt hot/cold, no rigors' but that now the pain was 'much better' and she was discharged with advice to return if she developed flu-like symptoms.

Shortly after returning home, the patient began to feel unwell and feverish. She phoned the urology ward twice and was reassured each time. Eventually her partner phoned an ambulance and she returned to the emergency department overnight, where her pulse rate was 124 min^{-1} and blood pressure 78/48 mmHg. She remained apyrexial with a temperature of 36.8°C, and repeat urine analysis remained negative for nitrites.

A repeat CTKUB confirmed that the stone was still causing mild left-sided hydronephrosis, and she was given i.v. meropenem. A stent was inserted which drained pus, and she was transferred postoperatively to intensive care where she unfortunately suffered a sepsis-induced myocardial infarction the following day.

Would the reader have been tempted to discharge the patient when she was reviewed in the morning? Is the process of 'safety-netting' robust enough to use in situations such as this? Clearly in this case the safety-netting did not work, and it would be difficult to argue any fault on the patient's side here.

Obstructed Infected Kidney Summary

We hope these cases will remind readers of the catastrophic potential outcomes of the obstructed infected kidney and the clinical vigilance that this condition demands, and highlight some of the logistical challenges we face in treating it.

Catastrophic sepsis-driven outcomes are relatively rare; a large-scale study in the USA estimated the mortality rate of infected urolithiasis at 0.2% [13]. Of course, beneath the tip of the iceberg of mortality probably lies a greater mass of morbidity. It is easy to forget how rapid the rate of progression of deterioration such cases can be.

A common theme of these cases is that none of these patients had nitrites on their urine analysis and none of them had a temperature above 37.5°C, and yet all of them were unquestionably and profoundly septic. Clinicians must have a high index of suspicion for the patient who might become rapidly unwell, even if they appear well on admission.

Finally, we acknowledge the logistical challenges that urologists face in treating these patients, from negotiations with

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interventional radiology, to inter-hospital cover and making the case for opening a second emergency theatre. The defence of hospital management is always that 'of course we would have opened a second theatre if only the doctor had told us how important it was', so take it upon yourself to ask politely but forcefully, documenting any resistance you might encounter. Few things are more frustrating than being unable to deliver time-critical treatment because of inefficient processes, and it is always worthwhile to ensure that local protocols are streamlined.

Discussion

In our view none of the cases described in this series are especially contentious. We are all taught to discuss every complication during consent, not to force a ureteroscope up a tight ureter and that an obstructed infected kidney needs urgent decompression. Stone surgery is too often deemed of trivial complexity and it is easy to become victims of our own success – to become so good at doing things right that we forget the stupidly simple ways in which we can avoid getting it wrong. Complacency is easy, especially when most of the time we get away with errors; most cases do not end in litigation.

All of us from time to time err. We hope that this case series highlights the potentially catastrophic outcomes of even small errors of judgement. To paraphrase Benjamin Franklin, we hope this series of cases will allow the careful stone surgeon to learn from the experiences of those unfortunate others, and improve outcomes in the future.

Disclosures of Interest

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Abbreviations: CTKUB, CT of the kidneys and bladder; DSMA, dimercaptosuccinic acid; fURS, flexible ureteroscopy; PCNL, percutaneous nephrolithotomy.

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