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ORIGINAL ARTICLE

What is the impact of pulse modulation technology, laser settings and intraoperative irrigation conditions on the irrigation fluid temperature during flexible ureteroscopy? An in vivo experiment using artificial stones

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Abstract

Purpose To investigate the effect of different combinations of laser power settings and irrigation conditions using the pulse modulation technology of Quanta™ on irrigation fluid temperature (IFT) during FURS (flexible ureteroscopy) on an in-vivo porcine model with artificial stones.

Materials and methods A female pig was used. Following the insertion of artificial stones (Begostone™, BEGO USA, Lincoln, RI), a K-type thermocouple was fixed to the created percutaneous access tract. Real-time recordings of IFT during FURS were performed without UAS (ureteral access sheath), with 10/12 UAS, 12/14 UAS and 14/16 UAS. Stone fragmentation was achieved using Quanta Litho Cyber Ho 150 W™ (Samarate, Italy). The IFT was recorded for 30 s, during laser activation, with power settings of 20, 40, 60, 75 and 100 W under both manual pump and gravity irrigation.

Results The IFT rise above 54 °C was recorded above a power of 40 W when gravity irrigation was used. The use of UAS prolonged the time for IFT to reach high values, although high power settings increase IFT within seconds from the laser activation. Under pump irrigation, only the 100 W power setting without the use of UAS resulted in dangerous IFT after approximately 10 s.

Conclusion The high-power Ho:YAG laser can cause a damaging thermal effect to the kidney exceeding the threshold of 54 °C, under gravity irrigation. Lower power settings (up to 40 W) can be used with safety. According to our experiment, when using high power settings, the use of UAS and manual pump irrigation, is the safest combination regarding renal thermal damage.

Keywords Temperature · Pig · Laser · Ureteroscopy · Artificial · Stone

Abbreviations

FURS	Flexible ureteroscopy
IFT	Irrigation fluid temperature
IRT	Intrarenal temperature
IRP	Intrarenal pressure
RIRS	Retrograde intra-renal surgery
UAS	Ureteral access sheath
Ho:YAG	Holmium:yttrium–aluminum–garnet
GI	Gravity irrigation
MPI	Manual pump irrigation
AS	Artificial stone

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Introduction

The new high power holmium (Ho:YAG) laser pulse modulation technology (Quanta Cyber:Ho 150 W™) is expected to be more efficient in terms of lithotripsy, making endourology procedures faster and easier [1]. Nevertheless, these high-power devices are newly introduced and many changes are expected to be seen in the clinical practice. Thus, although the boosted efficacy regarding energy delivery and retropulsion reduction, there are not sufficient data regarding the renal thermal effect in the kidney during FURS [2]. In addition, it remains unclear whether the different pulse modulation technologies have an impact to the IFT. The IFT elevation above a hazardous threshold during the procedure may cause immediate or delayed thermal injury to the renal parenchyma. The current study was planned to investigate the effect of the above high power laser system with pulse modulation in different combinations of laser power settings and irrigation conditions on IFT.

Methods

Stone creation

Rounded phantom stones made of BegoStone™ powder measuring 8.5 × 8.5 × 5.5 mm were created. The mixture was left to dry for 72 h in a plastic mold. The AS (artificial stones) were then moistened in a water tank for 1 h before the experiment, to fully simulate real the urinary tract stones within the urinary tract. The methods proposed by previously published studies were used [3, 4]. Hard stones (powder to water ratio 15:3) were preferred. In that way the experimental set up did not have to be often changed to replace the fragmented AS in the porcine pelvicalyceal system for the temperature measurement.

Preparation of the pig for the experiment

The pig was managed according to the available veterinary protocols.

Operative setup and technique

The pig was placed in supine position. Rigid cystoscopy was conducted for the identification of the ureteral orifices. A 0.035F guidewire (HiWire™ Nitinol Core Wire Guide, COOK Medical, Cook Ireland Ltd., Limerick, Ireland) was ascended to the right kidney under fluoroscopic guidance. An ureteral catheter was inserted over the wire and retrograde pyelography was performed. The animal was placed to prone position. A percutaneous access was achieved with an 18-gauge puncture needle by a fluoroscopy-guided technique. The access point was then dilated up to 30F and the 30F sheath was used to place the AS inside the upper calyx. One K-type insulated flexible metal thermocouple was placed in the upper calyx through the 30F sheath. A 18Fr nephrostomy (COOK Medical, Cook Ireland Ltd., Limerick, Ireland) was inserted through the 30F sheath. The balloon of the nephrostomy was inflated to stabilize the nephrostomy and the thermocouple inside the 30F sheath, providing also watertight sealing for the percutaneous tract. (Fig. 1) A Super stiff guidewire (Amplatz Super Stiff™, Boston Scientific, Marlborough, Massachusetts, USA) was inserted through the ureteral catheter in the kidney. This last step facilitated the insertion of the flexible ureteroscope without the UAS. The diameter of the UAS was increasing as the experiment was progressing. The AS was changed whenever significant decrease of its size was evident. The nephrostomy was deflated and removed with the thermocouple from the sheath. A new artificial stone was inserted into the kidney through the percutaneous sheath and the procedure was started over again. (Fig. 1).

Thermocouple and data logger

The SE001(Pico Technologies, Cambridgeshire, UK) thermocouple was employed. The device can record a wide range of temperature from − 60 to + 350 °C. The thermocouple was paired and connected to the data logger (TC08, Pico Technologies, Cambridgeshire, UK) for real-time temperature measurement. The data acquisition rate was set at 1 count/second.

Measurement of IFT

A 270 μm laser fiber was inserted and activated aiming the AS for 30 s while performing FURS using Pusen PU3022a flexible ureteroscope (Zhuhai Pusen Medical Technology Co.,China). This procedure was conducted without UAS, and with 10/12 UAS, 12/14 UAS, and 14/16 UAS (Flexor® Ureteral Access Sheath with AQ® Hydrophilic Coating, COOK Medical, Cook Ireland Ltd., Limerick, Ireland). Laser power and energy-frequency settings used were 20 W (1 J-20 Hz), 40 W (1 J-40 Hz), 60 W (2 J-30 Hz), 75 W (1.5 J-50 Hz) and 100 W (2 J-50 Hz) using the Quanta Cyber:Ho 150 W™(Samarate, Italy) laser system. The bags were placed 1 m over the table. The irrigation system used was Irrigation System™ (COOK Medical, Cook Ireland Ltd, Limerick, Ireland). The irrigation fluid was at room temperature (approximately 25 °C). Gravity irrigation(GI) and Manual pump irrigation(MPI) were used. The MPI rate was 1 pump every 3 s. The pulse mode used was Virtual Basket™, that combines a low retropulsion with a fragment suction effect. It consists of a double pulse emission. A first pulse generates the vapor bubble and a second pulse, emitted from the same fiber, propagates through the bubble to irradiate the stone [5]. IFT greater than 54 °C was considered unsafe for the kidney [6].

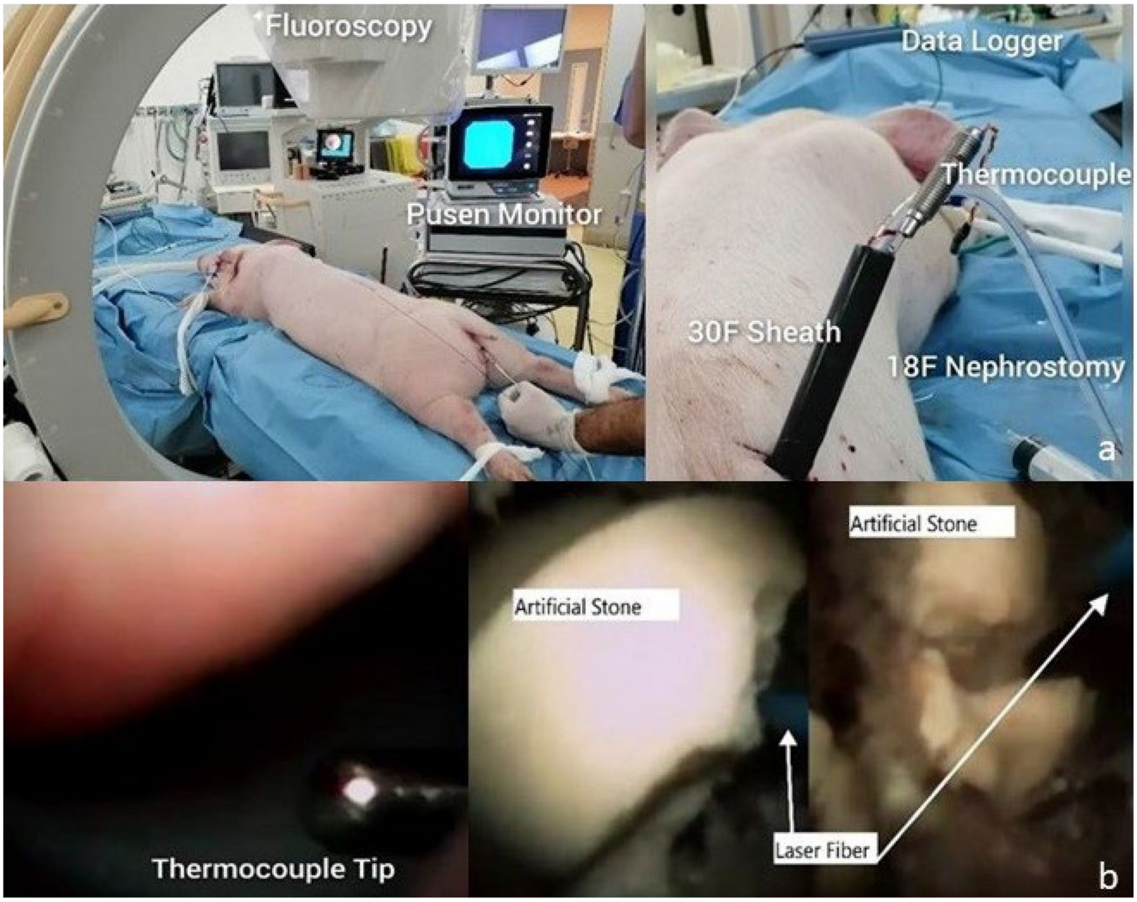

Fig. 1 **a** Photo of the set-up, after dilation of the upper calyx (30F sheath) and the thermocouple fixed inside the upper calyx. **b** The tip of the thermocouple inside the upper calyx and the artificial stone in different phases of fragmentation

Results

Gravity irrigation

The IFT without UAS did not exceed the unsafe threshold (54 °C), when laser power settings of 20 W were tested. IFT reached unsafe values rapidly, when higher than 40 W laser power settings were used (75 and 100 W). The use of a 10/12 UAS did not significantly change the results. The IFT exceeded the threshold in 30 s when using 60 W and in almost 5 s when using 75 and 100 W. When using the 12/14 UAS, the IFT remained in a safe zone at 20 and 40 W power settings, but the temperature exceeded the safety limits at 75 and 100 W. When using the 14/16 UAS, IFT was below the threshold at 20 and 40 W. However, the IFT was over 54 °C in roughly 15 s at 60, 75 and 100 W. It is worth noticing that the IFT was increasing faster, as the laser power increased. In addition, high power settings (> 60 W), with or without the use of UAS, lead to unsafe IFT (Fig. 2).

Manual pump irrigation

The IFT without UAS did not exceed 54 °C, except when the 100 W power settings were used for approximately 10 s. The IFT remained less than 54 °C at 20, 40, 60 and 75 W power settings for almost the entire laser activation time. The use of the UAS 10/12 was result in safe laser activation and never increased about safety limits. The use of 12/14 UAS and 14/16 UAS did not allow the IFT to reach potential harmful values, regardless of the power settings used. It seems that the size of UAS is not directly related to the maximum IFT value. When the 14/16 UAS was used, the IFT did not reach 40 °C over 30 s at 20, 40, 60 and 75 W, but the threshold was reached at 100 W (Fig. 2). Table 1 summarizes the maximum temperature during the experiment.

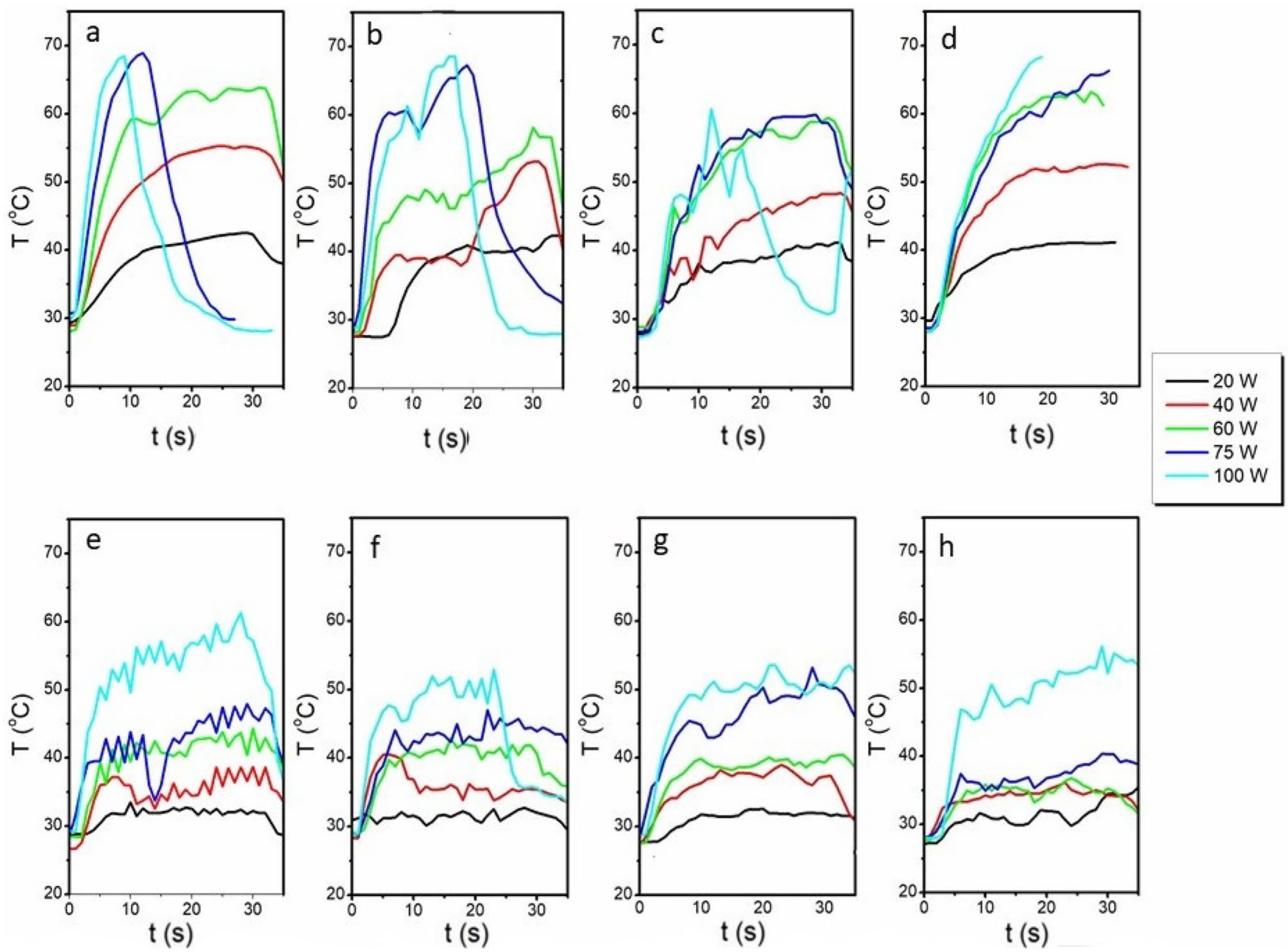

Fig. 2 First row: real-time irrigation fluid temperature recording during activation of 270-μm laser fiber under gravity irrigation at 20, 40, 60, 75 and 100 W for 30 s. **a** Without the use of UAS, **b** with the use of UAS 10/12, **c** with the use of UAS 12/14, **d** with the use of UAS 14/16. Second row: real-time irrigation fluid temperature recording during activation of 270-μm laser fiber under manual pump irrigation at 20, 40, 60, 75 and 100 W for 30 s. **e** Without the use of UAS, **f** with the use of UAS 10/12, **g** with the use of UAS 12/14, **h** with the use of UAS 14/16

Table 1 Presentation of the maximum irrigation fluid temperature and the exact second it was observed

Power (W)	Irrigation method	No-sheath		10–12		12–14		14–16	
		T_{max} (°C)	*t* (s)	T_{max} (°C)	*t* (s)	T_{max} (°C)	*t* (s)	T_{max} (°C)	*t* (s)
20	Gravity	42.6	30	42.4	30	41.2	30	41.2	30
	Pumping	33.52	30	32.7	30	32.6	30	35.7	30
40	Gravity	55.3	30	53.14	30	48.4	30	52.7	29
	Pumping	38.7	30	40.5	30	39	30	36.2	30
60	Gravity	63.8	30	58.14	30	59.3	29	63.4	24
	Pumping	44.3	30	42.9	30	40.5	30	36.8	30
75	Gravity	68.9	12	67.3	17	59.8	30	66.3	22
	Pumping	50	30	47	30	53.2	30	40.38	30
100	Gravity	68.4	9	68.6	19	60.6	12	68.4	20
	Pumping	61.3	30	52.9	30	53.5	30	56.1	30

Discussion

Pulse modulation technologies can, at least in theory, reduce the stone retropulsion and probably enhance efficiency of laser ablation. The plethora of modalities for lithotripsy may seem innovative, but the balance between safety and effectiveness can be fragile. Especially when considering the lack of data for the optimal use of the new high-power Ho:YAG laser systems. The aim of our study was to provide more information on the IFT during the activation of a high-power laser in an in vivo porcine model with AS, using a newly introduced pulse modulation technology. Many different combinations in terms of the type of irrigation, the presence and diameter of UAS and different laser power settings were investigated during FURS. The translational value of our research lies on identifying the optimal combination of laser settings, irrigation modality and UAS diameter to assure the safety of the patient during FURS with innovative high-power pulse modulation laser lithotripters.

In our study, the temperature of 54 °C was considered the reference value for thermal injury. Available data suggest that the proteins of the urinary tract begin to denaturate at the temperature of 43 °C [7]. The temperature of 54 °C is the threshold for the necrosis of coagulative tissues in porcine kidney [6]. According to this, GI is a potentially dangerous option of irrigation during FURS, especially when used with power setting above 60 W. The addition of UAS to the operational set up did not contribute to better thermal conditions. The time needed to reach 54 °C was shortly prolonged as the diameter of the UAS increased. Nevertheless, the 75 W and 100 W settings seemed to cause much more heat production which resulted in an immediate development of high temperatures even with the presence of UAS. Thus, the lack of forced irrigation, when power settings higher than 40 W are used, cannot be recommended. The addition of UAS did not change the increasing temperature situation significantly.

The relationship between temperature alteration and the condition of irrigation is established. Numerous studies have investigated this kind of correlation. In a study by Hein et al. a porcine kidney was used for measuring the temperature during FURS. The kidney was placed into water and a thermocouple was placed near the laser fiber. They used 5–100 W power settings and 0–100 ml/min irrigation rate. It seems that the temperature is elevated, when irrigation is not enough [8]. In another study by Maxwell et al. the authors pursued the simulation of calyx, pelvis and ureter in vitro. The power settings used were 5–40 W and the irrigation flow 0–40 ml/min. The temperature was measured during laser activation and the results showed that the elevation of IRT (intra-renal temperature) is related with the height of the laser power and the reduction of IRT with the pressure of irrigation flow [9]. A study in the same topic has been reported by Winship et al. An in vitro model of the ureter and the renal pelvis was created, to perform FURS. An 11/13 UAS and a thermocouple were used to measure the temperature during the procedure. The power setting range was between 3.6 and 20 W and the irrigation pressure used was 0, 100 and 200 mmHg. The results go with the previously mentioned data. Finally, it seems that there is a straight correlation between the increase of laser power and the increase of the IRT and between the increase of irrigation pressure and the reduction of the IRT [10].

In a previous experimental study of our group, we used the same experimental conditions to measure the IFT. The power settings did not match the current settings and we observed that the temperature does not reach dangerous values in the porcine pelvis. Nevertheless the Ho:YAG laser power settings did not exceed 20 W [11]. In our last in vivo study we investigated the correlation of irrigation parameters and UAS size on the IRT during FURS with a high-power laser in vivo using the same operative setup. Under GI without UAS, the IRT exceeded the threshold in 20 s, even at 20 W. The use of UAS held the temperature under 54 °C at 20 W. In addition, IRT was rapidly elevated when a power of 60 W was used. MPI seems to be safer, as IRT remained in the safe zone even at 60 W. The main limitation of this study was the absence of the stone [12]. In the current experiment the temperature remained in the safe limits under GI, with or without the use of UAS, for power settings up to 40 W. Additionally, the IFT reached the threshold under MPI, only when the laser power reached 100 W without UAS and with 14/16 UAS. This happened in the first 10 s of laser activation. The presence of the AS and the pulsatile release of energy to the stone may explain the presented results.

The mentioned data imply that the safest and most efficient combination for FURS is the insertion of UAS with forced irrigation. Nevertheless, the increase of intrarenal pressure during FURS under forced irrigation may lead to post-operative complications [13, 14]. The use of UAS not only reduces the possibility of thermal injury due to IFT reduction, but also reduces the risk of fever and sepsis by reducing the IRP (intra-renal pressure) [15, 16].

To our knowledge, the current in vivo study is the first one to investigate the effect of different laser power settings on IFT under different irrigation conditions during FURS with the presence of an AS inside the porcine pelvicalyceal system. As every experimental study, the current one has limitations. Firstly, it seems that a mechanically ventilated pig under general anesthesia actually presents the heatsink effect of renal blood flow. The experimental set up was identical to the clinical one and the instruments were the same that are used for real cases. During FURS, it is difficult to keep the laser tip steady as the patient is breathing under general anesthesia and to maintain the same distance between the laser tip and the thermocouple during the operation. As a result, some minor fluctuations could be justified in this real-time temperature recording. The results presented should be considered reliable, as consistency was achieved after multiple repeat recordings and measurements. In addition, it is known that in the clinical practice the prolonged laser activation (> 10 s) is not used, as the consecutive energy delivery causes the production of dust and the visibility could be limited. These clues offer credibility to our data. Despite these limitations, our study provides valuable data for the safe and efficient use of the high-power Ho:YAG laser.

Conclusion

The introduction of high-power Ho:YAG laser could potentially be harmful due to its thermal effect when used under GI. Our study suggests that the presence of UAS does not significantly improve the results. High-power settings (> 60 W) are safe when a combination of pump irrigation flow and UAS is applied. MPI seems an excellent solution for maintaining the IFT in the safe zone. The addition of UAS offers the advantage of reduction of the IFT and the IRP during FURS.

Author contributions AP—Data collection and analysis, manuscript writing. KP—Data collection. AV—Data collection. CA—Data collection. AT—Data analysis and manuscript editing. BM—Data analysis. GK—Data collection. EF—Data analysis. EL—Project development, manuscript editing. PK—Project development, data analysis and manuscript editing.

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Declarations

Conflict of interest The authors declare no conflict of interest.

Ethical standards The study has been carried out in accordance with the ethical standards laid down in the 1964 Declaration of Helsinki and its later amendments.

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