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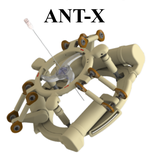
Robotic-assisted fluoroscopic guidance provides more accurate and confident renal access than ultrasound guidance: a phantom benchtop study

Kazumi Taguchi, Shuzo Hamamoto, Tomoki Okada, Kengo Kawase, Teruaki Sugino, Yutaro Tanaka, Rei Unno, Taiki Kato, Ryosuke Ando, Atsushi Okada, and Takahiro Yasui

Department of Nephro-urology, Nagoya City University Graduate School of Medical Sciences

Introduction and objectives

- Renal access is the most important step for successful percutaneous nephrolithotomy (PCNL).
- Several techniques have been developed to improve the accuracy for renal access; however, the state-of-the-art technology with artificial intelligence (AI) may bring a better feature of completely automated puncture.
- The automated needle targeting with X-ray (ANT-X) (NDR Medical Technology) was developed for providing an optimal renal access with angle calculation by AI.
- To evaluate the feasibility of robotic assisted fluoroscopic-guided (RAFG) puncture, we compared RAG, utilizing a novel robot system for percutaneous renal access, with ultrasound-guided (USG) puncture.



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Materials and Methods

- ***Study design***

-This prospective, single-center, bench-top study using renal phantom models was conducted at Nagoya City University (NCU) Hospital. Seventeen urologists, consisting of 12 residents and 5 attending surgeons from the NCU Hospital, participated in this study.

- ***Phantom model***

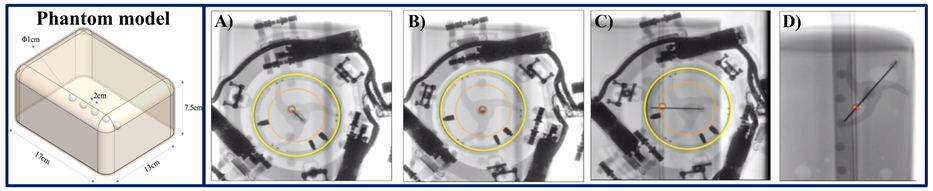
-A 3D non-anthropomorphic phantom was designed by the NDR Medical Technology (below).

- ***USG puncture***

-We utilized a US machine (ARIETTA 70: Hitachi, Ltd) to visualize the target balls and perform needle access.
-Each participant performed the USG puncture both with and without a needle guide attachment .

- ***RAFG puncture***

-We utilized the ANT-X used for fluoroscopy-guided PCNL with bull's eye technique.
-After the initial marking on the phantom skin, computerized calibration (A) and alignment (B) were carried out to decide the needle insertion angle. Then, the needle was advanced deep into the phantom model toward the target ball (C). The puncture location was confirmed under fluoroscopic guidance by tilting the C-arm (D).



- ***Clinical validation on Randomized Controlled Study***

-In order to validate the feasibility of RAFG PCNL, we conducted a preliminary comparison study between RAFG and USG PCNL for patients with large renal stones at the NCU Hospital (IRB-approved).
-Patients were randomized divided into two groups, RAFG and USG, then undergone for mini-PCNL with ureteroscopy assistance.
-We utilized ARIETTA ® for USG and ANT-X for RAFG, a 16.5/17.5Fr tract for a nephroscope, and LithoClast® for lithotripsy. Since we had no prior experience of fluoroscopic-guided PCNL, we had a trial case for practice before starting this preliminary study.

Results

Phantom Benchtop Study

Table1: Comparison of feasibility of access between USG and RAFG punctures

OUTCOMES	USG puncture	RAFG puncture	P value
	n=34	n=17	
single puncture success (%)	24 (70.6)	17 (100.0)	0.021
device set up time (sec)	30.5 [23.0, 42.8]	93.0 [68.0, 102.0]	<0.001
needle puncture time (sec)	46.0 [37.3, 96.8]	35.0 [28.0, 37.0]	<0.001
total procedure time (sec)	85.5 [62.8, 137.0]	126.0 [104.0, 132.0]	0.054
duration of fluoroscopic exposure (sec)	6.5 [4.0, 10.0]	38.0 [30.0, 58.0]	<0.001
Location of a target ball (%)			
most lateral	3 (8.8)	2 (11.8)	0.255
lateral	22 (64.7)	7 (41.2)	
center	9 (26.5)	8 (47.1)	

- The single puncture success rates of the RAFG and USG puncture were 100% and 70.6%, respectively.
- The median needle puncture time of RAFG was 24% shorter than that of USG.
- The median duration of fluoroscopic exposure of RAFG was longer than USG.

- The surgeon's self-assessment demonstrated that participant urologist felt better visibility, safer, and more satisfied with RAG than USG punctures.

Table2: Comparison of surgeon's self-assessment after each procedure

SELF ASSESSMENT		USG puncture	RAFG puncture	P value
		n=34	n=17	
Visibility (%)	1	1 (2.9)	0 (0.0)	0.002
1, hardly detectable	2	6 (17.6)	0 (0.0)	
2, poor	3	19 (55.9)	5 (29.4)	
3, reasonable	4	7 (20.6)	5 (29.4)	
4, good	5	1 (2.9)	7 (41.2)	
5, excellent				
Maneuverability (%)	1	0 (0.0)	0 (0.0)	0.229
1, very difficult	2	5 (14.7)	0 (0.0)	
2, somehow difficult	3	8 (23.5)	4 (23.5)	
3, fine	4	13 (38.2)	5 (29.4)	
4, smooth	5	8 (23.5)	8 (47.1)	
5, very smooth				
Safety (%)	1	1 (2.9)	0 (0.0)	0.013
1, almost failed	2	6 (17.6)	0 (0.0)	
2, with some troubles	3	11 (32.4)	3 (17.6)	
3, fine	4	11 (32.4)	4 (23.5)	
4, with a few confirmations	5	5 (14.7)	10 (58.8)	
5, without any trouble				
Satisfaction (%)	1	2 (5.9)	0 (0.0)	0.001
1, may need to re-try	2	7 (20.6)	0 (0.0)	
2, poor but no need to re-try	3	16 (47.1)	3 (17.6)	
3, average	4	8 (23.5)	8 (47.1)	
4, better than average	5	1 (2.9)	6 (35.3)	
5, excellent				

Clinical Trial

Figure1: RAFG punctures during PCNL

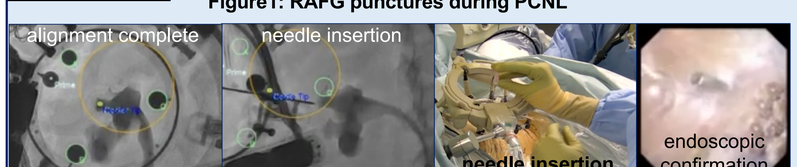


Table3: Patients' characteristics between USG and RAFG PCNLs

		USG PCNL	RAFG PCNL	P value
		n=7	n=7	
age	years old	58.7 (9.3)	54.4 (16.2)	0.556
male sex (%)		5 (71)	1 (14)	0.103
BMI	kg/m^2	25.7 (4.6)	22.6 (4.2)	0.211
laterality (%)	Rt: Lt	2 (29) : 5 (71)	4 (57) : 3 (43)	0.592
hydronephrosis (%)	Grade 0, 1, 2	4 (57) , 2 (29) , 1 (14)	3 (43), 1(14), 2(29)	0.633
staghorn (%)		2 (29)	2 (29)	1
stone density	HU	1116 [833, 1230]	1192 [907, 1466]	0.655
stone volume	mm^3	3456 [3018, 26464]	6000 [41423, 19863]	0.565

Table4: Outcome comparison between USG and RAFG PCNLS

		USG PCNL	RAFG PCNL	P value
		n=7	n=7	
puncture calyx (%)	upper	2 (29)	2 (29)	0.16
	middle	3 (43)	0 (0)	
	lower	2 (29)	5 (71)	
number of punctures per case		2.0 [1.0, 2.0]	1.0 [1.0, 1.5]	0.43
devise set-up duration	min	4.0 [3.5, 6.0]	4.0 [3.0, 5.0]	0.796
puncture duration	min	9.0 [6.0, 16.5]	4.0 [3.5, 9.0]	0.336
total surgical duration	min	86 [79.50, 94.50]	111 [92, 149]	0.337
fluoroscopy duration	min	7.8 [6.3, 9.5]	12.3 [9.2, 17.6]	0.086
residual stone after 1 month of surgery (%)	none	4 (57)	3 (43)	0.143
	<4mm	1 (14)	4 (57)	
	>4mm	2 (29)	0 (0)	

- No differences in patients' characteristics were seen between the two groups.
- While no differences were observed between two groups, the median number of punctures in the RAFG group was once whereas that in the USG group was twice.
- The fluoroscopy duration was correlated with the stone volume and total surgical duration ($p<0.001$ for both).

Conclusions

- Our study revealed that although the RAFG and USG punctures had comparable performance, the RAFG puncture may be safer and more accurate than USG puncture for renal access. The RAFG will be a new option with basically zero learning curve, which can be adapted by beginners.