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CLINICAL INVESTIGATION INTERVENTIONAL ONCOLOGY

Usefulness of a Pretreatment CT-Based Modified RENAL Nephrometry Score in Predicting Renal Function After Cryotherapy for T1a Renal Mass

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Abstract

Purpose We investigated the usefulness of the modified RENAL nephrometry (mRN) scoring system for predicting post-cryotherapy renal function in patients with T1a renal mass.

Patients and Methods A total of 75 patients with a T1a renal mass were enrolled. The mRN score was determined based on the tumor size, the tumor's exophytic/endophytic properties, the tumor's nearness to the collecting system, and the anterior/posterior location of the kidney. The change in the estimated glomerular filtration rate (ΔeGFR) was calculated as follows: ΔeGFR = 100 × ([pretreatment eGFR − eGFR at 6 months after cryotherapy]/pretreatment eGFR). Based on the ΔeGFR results, we classified the patients into two groups: a preserved renal function group (ΔeGFR $<$ 10%) and an impaired renal function group (ΔeGFR $\geq$ 10%). We then analyzed the relationships between the mRN score and ΔeGFR and between the mRN score and the chronic kidney disease (CKD) stage.

Results The mean ΔeGFR for all patients was 5.5%. The mRN scores of the preserved renal function group (5.8 ± 0.3) were significantly lower than those of the impaired group (7.4 ± 0.3) ($p < 0.001$). When the mRN score cutoff value was set at 7 points, the mRN had 67.7% sensitivity, 72.7% specificity, 61.8% positive predictive value (PPV), 76.1% negative predictive value (NPV), and 70.7% accuracy for predicting impaired renal function. For predicting a deterioration of CKD stage, the mRN had 92.9% sensitivity, 67.2% specificity, 39.4% PPV, 97.6% NPV, and 72% accuracy.

Conclusion Our newly proposed modified RENAL nephrometry score was suggested to be useful for predicting renal function after renal cryotherapy.

Keywords Renal cell carcinoma · Renal function · Cryoablation · Computed tomography

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Introduction

Cryoablation is an accepted alternative therapy for small renal cell carcinoma (RCC), and its outcomes are comparable to those of surgical treatment [1–3]. Originally, cryoablation was considered not to affect renal function, but a careful review of more recent reports indicates that the renal function of patients who underwent cryoablation was somewhat worsened. Buy et al. [3] reported that although renal function was preserved in approximately 80% of patients treated by cryoablation, 20% of the patients showed a worsening of their chronic kidney disease (CKD) stage. Anou et al. [4] reported a significant decrease in the mean estimated glomerular filtration rate (eGFR). Indeed, in daily practice we sometimes encounter patients with significant worsening of renal function after treatment. To the best of our knowledge, there is no system that predicts the deterioration of renal function.

The RENAL nephrometry scoring system characterizes the renal tumor anatomy based on the radius (R) (largest diameter of the tumor in any single plane), the tumor's exophytic/endophytic (E) properties, the nearness (N) of the tumor to the collecting system or sinus in millimeters, the anterior (A)/posterior location, and the tumor's location (L) relative to polar lines [5]. Kopp reported that a RENAL score ≥ 10 was independently associated with de novo CKD at 6 months [6].

The RENAL system was established based on cases undergoing surgical treatment, and thus, it does not apply to percutaneous cryoablation. A more detailed stratification is thus needed for application of the RENAL system to cryotherapy. Accordingly, in the present study we developed a modified RENAL nephrometry scoring system and examined its utility for predicting renal function.

Patients and Methods

The retrospective design of the study was approved by the Institutional Ethics Committee, and the requirement for informed written consent was waived.

Patients

Between April 2014 and March 2017, 102 consecutive patients underwent cryoablation for one or more renal tumors measuring ≤ 4 cm in diameter. They were all non-surgical candidates. The inclusion criteria of this study were as follows: (1) sufficient follow-up of > 6 months without local recurrence; (2) a single tumor treated by a single session of cryoablation; (3) no history of dialysis; and (4) no pretreatment of angiography with Lipiodol marking. The exclusion criteria were as follows: repeated cryoablation due to local recurrence or residual tumor ($n = 12$); insufficient follow-up ($n = 11$); dialysis ($n = 2$); and pretreatment of angiography with Lipiodol marking ($n = 2$).

The Modified RENAL Nephrometry (mRN) Score

The details of the scoring system are summarized in Table 1. The size variable (R) was modified as described previously: For the radius (R factor), 1 point is given for tumors ≤ 3 cm, and 2 points are given for tumors > 3 cm but ≤ 4 cm [7]. As for the tumor's location relative to the polar line (L factor), it can be assumed that this factor affects neither the technical difficulty nor renal function in cryoablation, and thus 0 points are given to all tumors.

Cryoablation

Cryoablation was performed under conscious sedation and local anesthesia by at least one of four interventional radiologists (Y.A, Y.U, D.O, and K.M with 24, 19, 15, and 7 years of experiences, respectively). An argon-based cryoablation machine (CryoHit; Galil Medical, Yokneam, Israel) with a 17-gauge cryoprobe was used for all patients under computed tomography (CT) guidance (Aquilion; Toshiba Medical Systems, Otawara, Japan). A biopsy was performed during the cryoablation session. The number and the type of cryoprobes were chosen to achieve optimal coverage of the tumor by the ice-ball method [3]. A hydrodissection technique was used when vulnerable organs were close to the tumor. Cryoablation was performed in two cycles of 10 min of freezing and 5 min of thawing. CT images were obtained at the end of the second cycle of cryoablation to confirm that the ice ball completely covered the tumor with a margin of ≥ 5 mm [3, 8].

Renal Function

The change in the estimated glomerular filtration rate (ΔeGFR) was calculated as follows: ΔeGFR = 100 × ([eGFR at pretreatment − eGFR at 6 months after cryotherapy]/eGFR at pretreatment). On the basis of the ΔeGFR, we classified the patients into two groups: a preserved renal function group (ΔeGFR $< 10\%$) and an impaired renal function group (ΔeGFR $\geq 10\%$). We also evaluated the CKD stage based on the eGFR level before

Table 1 Modified RENAL nephrometry scoring system

	Score 1	Score 2	Score 3
R: Radius: Tumor maximum diameter (r, cm)	$\leqq 3$ cm	3 cm $< r \leqq$ 4 cm	
E: Exophytic/endophytic properties	$\geqq 50\%$	$< 50\%$	Entirely endophytic
N: Nearness of the tumor to the collecting system (n)	$\geqq 7$ mm	4 mm $\leqq n <$ 7 mm	$\leqq 4$ mm
A: Anterior/posterior + X*	Posterior + X	Anterior	
L: Location relative to the polar line	N/A	N/A	N/A

*X is assigned when the tumor grows from the tips of the renal poles

cryoablation and 6 months after treatment, using the Kidney Disease: Improving Global Outcomes (KDIGO) Clinical Practice Guidelines [9]; stage 1, ΔeGFR ≥ 90; stage 2, 60–89; stage 3, 30–59; stage 4, 15–29; stage 5, < 15.

Evaluation and Statistical Analysis

We analyzed the relationship between the mRN score and ΔeGFR values. Using the median mRN score as the cutoff value, we calculated the sensitivity, specificity, positive predictive value, negative predictive value, and accuracy of the mRN score for predicting renal impairment and worsening of CKD stage. We also calculated these values using the original RENAL nephrometry score. McNemar's test was used to determine if there were differences between mRN system and original RENAL nephrometry score system. Continuous variables were tested using Student's *t* test or the Kruskal–Wallis test. The level of significance was set at $p < 0.05$ for all tests. JMP 13.0 software (SAS Institute, Cary, NC) was used for the analyses.

Results

A final total of 75 patients were enrolled. The number of patients with solitary kidney was nine. Three tumors were cystic RCCs. The technical success rate was 100%. Four grade 3 complications, which consisted of retroperitoneal abscess in two cases and intestinal perforation in two cases (Common Terminology Criteria for Adverse Events), occurred after the procedures (5.3% complication rate). No biopsy-related complication such as bleeding that obscured tumor margins was encountered. The patients' characteristics are summarized in Table 2.

Table 2 Patient demographics and clinical data

Characteristics	Value
Age, median (range)	68 (30–90)
Gender (male:female)	59:16
Tumor size (mm), mean ± SD	23.8 ± 8.3
Number of kidneys (one:two)	9:66
Renal mass biopsy	
Total	72
RCC, clear cell carcinoma	60
RCC, papillary carcinoma	3
Oncocytoma	1
Atypical cell	2
Non-diagnostic	6
No biopsy	3
Grade 3 or more complication after therapy	4
Renal function	
eGFR (ml/min/1.73 m^2, mean ± SD)	
Pretreatment	62.0 ± 22.5
Post-treatment	57.9 ± 21.8
Stage of chronic kidney disease	
Pretreatment 1:2:3:4:5	9:29:33:4:0
Post-treatment 1:2:3:4:5	5:30:36:4:0
CKD stage change after treatment	
Deterioration:stable:improvement	14:54:7

ΔeGFR and CKD Status

For the total patient series, the mean pretreatment and post-treatment eGFR values were 62.0 ± 22.5 mL/min/1.73 m^2 and 57.9 ± 21.8 mL/min/1.73 m^2, respectively (Table 2), and the mean ΔeGFR was 5.5 ± 14.6% (range − 29.9 ± 40.9). The numbers of patients at each CKD stage (stages 1, 2, 3, 4, and 5) pretreatment were 9, 29, 33, 4, and 0, and at 6 months after the cryoablation treatment these patient numbers were 5, 30, 36, 4, and 0, respectively. The numbers of patients showing deterioration, stability, and improvement of CKD stage after cryoablation were 14 (18.7%), 54 (72%), and 7 (9.3%), respectively. There was no significant age difference between the preserved renal function group (69.5 ± 15.1 yrs) and the impaired renal function group (64.7 ± 12.6 yrs) ($p = 0.140$). There was also no significant ΔeGFR difference between the aged group (≥ 75 yrs old, 5.1 ± 16.0) and the younger group (< 75 yrs old, 5.7 ± 14.0) ($p = 0.562$).

The mRN Scoring System Factors and ΔeGFR

The relationships between the five mRN factors and the ΔeGFR are summarized in Table 3. There were significant correlations between the ΔeGFR and tumor growth properties (exophytic/endophytic), the nearness of the tumor to the collecting system, and anterior/posterior location. The ΔeGFR was higher in larger tumors, although these differences did not reach significance. The location relative to the polar line (L factor) was not correlated with the ΔeGFR.

Prediction of Renal Function

The mean (± standard deviation) and median mRN scores were 6.5 ± 1.6 and 7 (range 4–10), respectively, and the preserved group's mRN score ($n = 44$, 5.8 ± 0.3) was significantly lower than that of the impaired renal function group ($n = 31$, 7.4 ± 0.3) ($p < 0.001$). The mean (± standard deviation) and median original RENAL nephrometry scores were 6.7 ± 2.0 and 7 (range 4–10),

Table 3 Tumor demographics according to the mRENAL score

Variables	Number of cases	ΔeGFR	*p* value
(R) Tumor size			
≤ 3 cm	58	3.9 ± 1.9	0.079
3–4 cm	17	11.0 ± 3.5	
(E) Growth properties of the tumor			
Exophytic ≥ 50%	34	0.82 ± 2.4	0.033
Exophytic < 50%	21	8.3 ± 3.1	
Endophytic	20	10.6 ± 3.2	
(N) Nearness of the tumor to the collecting system			
≥ 7 mm	31	3.7 ± 2.5	0.008
4–7 mm	10	5.0 ± 4.4	
≤ 4 mm	34	10.2 ± 2.4	
(A) Anterior/posterior/*X*			
P + *X*	46 (35 + 11)	1.9 ± 2.1	0.006
A	29	11.3 ± 2.6	
(L) Location relative to the polar line			
Above/below the polar line	36	6.0 ± 2.5	0.893
Crosses the polar line	15	3.9 ± 3.8	
Between the polar line	24	5.8 ± 3.0	

respectively, and the preserved group's original RENAL nephrometry score (6.2 ± 0.3) was significantly lower than that of the impaired renal function group (7.5 ± 0.3) ($p = 0.004$). When the median mRN score of 7 points was used as the cutoff value, the mRN exhibited 67.7% sensitivity, 72.7% specificity, 63.6% positive predictive value (PPV), 76.2% negative predictive value (NPV), and 70.7% accuracy for predicting renal impairment (ΔeGFR ≥ 10%). On the other hand, when the original RENAL nephrometry system was used with a median score of 7 points as a cutoff, the system had 64.5% sensitivity, 59.1% specificity, 52.6% PPV, 70.3% NPV, and 61.3% accuracy (Table 4) for predicting renal impairment (ΔeGFR ≥ 10%). For predicting a worsening of CKD stage, the mRN scoring system had 92.9% sensitivity, 67.2% specificity, 39.4% PPV, 97.6% NPV, and 72% accuracy, whereas the original RENAL scoring system had 85.7% sensitivity, 57.4% specificity, 29.3% PPV, 94.6% NPV, and 62.7% accuracy (Table 5). All values in the mRN system were superior to those in the original RENAL system. Representative cases are presented in Figs. 1 and 2.

Table 4 Relationship between mRN score and ΔeGFR and between original RENAL score and ΔeGFR

	ΔeGFR		
	Impaired renal function group	Preserved renal function group	Total
mRN score			
≥ 7	21	12	33
< 7	10	32	42
Total	31	44	75
Original RENAL score			
≥ 7	20	18	38
< 7	11	26	37
Total	31	44	75

	Sensitivity	Specificity	PPV	NPV	Accuracy
mRN (%)	67.7	72.7	63.6	76.2	70.7
Original RENAL	64.5	59.1	52.6	70.3	61.3
p value	0.564	0.0143	N/A	N/A	0.0196

Table 5 Relationship between mRN score and changes in CKD status and between original RENAL score and changes in CKD status

	Changes in CKD status		
	Deterioration	Preserved (stable + improvement)	Total
mRN score			
≥ 7	13	20	33
< 7	1	41	42
Total	14	61	75
Original RENAL score			
≥ 7	12	26	41
< 7	2	35	34
Total	14	61	75

	Sensitivity	Specificity	PPV	NPV	Accuracy
mRN (%)	92.9	67.2	39.4	97.6	72.0
Original RENAL (%)	85.7	57.4	29.3	94.6	62.7
p value	0.317	0.0588	N/A	N/A	0.0339

Discussion

In our present retrospective analysis, although the mean ΔeGFR was low at 5.5 ± 14.6%, 14 of 75 patients (18.7%) exhibited a worsening of CKD stage. The mRN scores in the patients with impaired renal function were significantly higher than those of the patients with preserved renal function. All values in the mRN system were superior to those in the original RENAL system. In particular, the mRN system showed high sensitivity (92.9%) and high NPV (97.6%) for forecasting the worsening of CKD stage. In a clinical setting, this CT-based mRN score is easy to assign and could aid in the selection of patients for cryoablation. This system may be especially useful in the cases of non-dialysis patients with advanced-stage CKD. It can be used to assess the risk of introducing dialysis even after cryoablation, which had been believed to not affect renal function. In the majority of patients with good renal function, this system does not change the treatment modality; however, we should pay special attention to patients with high mRN scores in order to reduce renal damage, using minimal needle penetration of the kidney and providing a necessary and sufficient safety margin.

Buy et al. reported that approximately 80% of the patients showed “no change” or “improvement” of CKD stage after cryotherapy. They considered these results a favorable effect of the cryoablation. We agree with their results; our study also demonstrated that 61 of the 75 patients (81.3%) showed “no change” or “improvement.”

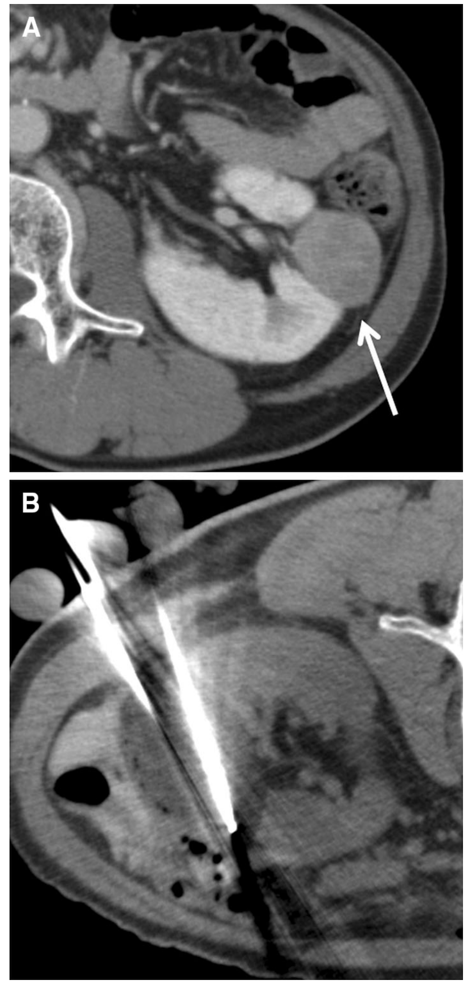

Fig. 1 A 71-year-old male with left RCC. **A** Contrast-enhanced CT shows a hypoattenuating mass (*arrow*) measuring 34 mm (R score = 2). The tumor is located in the anterior aspect of the kidney (A score = 2) with exophytic property (E score = 1) adjacent to the renal hilum (N score = 3). The mRN score was high at 8. The eGFR values at pre- and post-treatment were 65 mL/min/1.73 m^2 and 50 mL/min/1.73 m^2, respectively (ΔeGFR = 23%). The CKD stage declined from 2 to 3. **B** Note that the cryoprobe penetrated the posterior aspect of the kidney

We also focused on the 14 of 75 patients (18.7%) who showed a deterioration of renal function stage (Table 5).

In the mRN system, the tumor diameters are classified based on a 3-cm cutoff [7]. In order to achieve good local control, normal renal tissue must be sacrificed, and this leads to reduced renal function [10]. Even though the tumors in our patient series were all treated using the same safety margin (≥ 5 mm), the volume of sacrificed renal tissue depends on the tumor diameter; that is, the longer the tumor diameter is, the larger the sacrificed volume will be. In the patients with RCC treated by partial nephrectomy, tumor size is also a risk factor for postoperative renal failure after partial nephrectomy [11], and our present findings are consistent with this conclusion.

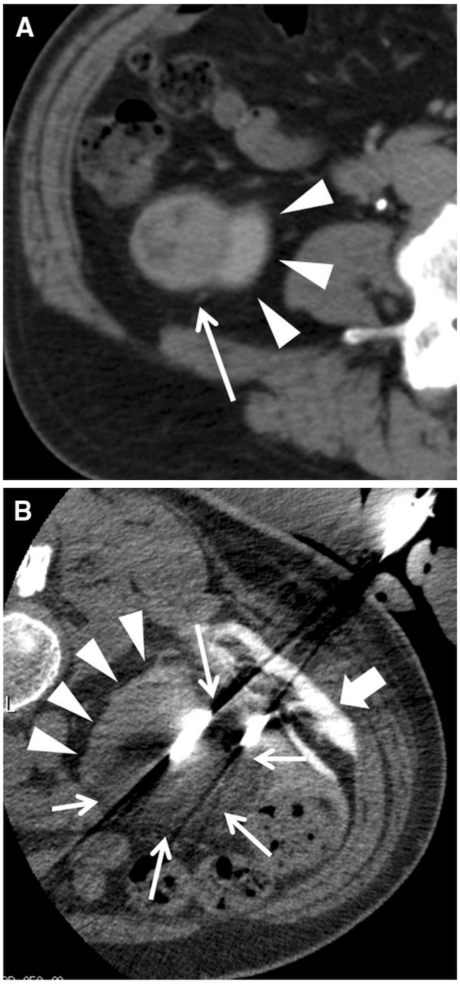

Fig. 2 A 68-year-old male with right RCC. **A** Contrast-enhanced CT shows a hypoattenuating mass (*arrow*) measuring 36 mm (R score = 2). *Arrowheads* indicate normal renal parenchyma. The tumor is located at the lower pole of the kidney, i.e., an *X* position (A score = 1) with exophytic property (E score = 1), 16 mm to the renal hilum (N score = 1). The mRN score was low at 5. The pre- and post-treatment eGFR values were 36 mL/min/1.73 m^2 and 34 mL/min/1.73 m^2, respectively (ΔeGFR = 5.6%). The CKD stage was stable at 3. **B** Note that the cryoprobe did not penetrate the renal parenchyma (*arrowheads*), and only a small volume of renal parenchyma was involved in the ice ball showing a hypoattenuating area (*arrows*). Hydrodissection was performed to protect the adjacent structure (*thick arrow*)

We observed in this study that the tumor's growth properties (the E factor), the nearness of the tumor to the collecting system (N factor), and the anterior/posterior location (A factor) had close correlations with the changes of renal function. We assumed that this is because the farther the cryoprobe penetrates the renal parenchyma, the greater the renal damage becomes. Notably, the original RENAL nephrometry score does not assign a point to any tumors at an anterior/posterior location (A factor). However, because cryoablation is usually performed by a posterior approach, the cryoprobe usually follows a path through the posterior or lateral aspect of the normal parenchyma to reach a tumor at an anterior location. We therefore give 2 points in the mRN system to tumors in an anterior location (and 1 point for a posterior or *X* location).

As for the L factor, the original RENAL nephrometry scoring system assigns points because non-polar solid renal masses have been shown to present a greater challenge during a partial nephrectomy [5]. In contrast, we did not include the L factor in the mRN scoring system (all cases received 0 points), because the location relative to the polar line was easily expected not to influence the ΔeGFR. In fact, our analyses demonstrated that the ΔeGFR was not correlated with the tumor location relative to the polar line (Table 3).

Gahan et al. [7] proposed another mRN score system in which only the R factor was adjusted; tumors were given an R score of 1 when they were < 3 cm, a score of 2 when 3–4 cm, and a score of 3 when > 4 cm. Other RENAL variables were unchanged. With their system, it had 92.9% sensitivity, 57.4% specificity, 33.3% PPV, 97.2% NPV, and 64% accuracy for predicting impaired renal function. For predicting a worsening CKD stage, their system had 67.7% sensitivity, 59.1% specificity, 53.8% PPV, 72.2% NPV, and 62.7% accuracy. Our system was also superior to Gahan's system.

In the present study, nine of 75 patients had solitary kidney, although we did not include solitary kidney as a new factor in this mRN scoring system. The renal function after cryoablation in patients with solitary kidney is still controversial. Raman et al. [12] reported that patients with renal tumors in solitary kidney not only exhibit a baseline deficiency in renal function but also are susceptible to further decrement in function following interventional therapy. In contrast, Weisbrod reported that there was no statistically significant change in GFR among the patients treated by cryoablation for a single tumor in solitary kidney [13]. There was also no statistically significant difference in the mean ΔeGFR between the patients with two kidneys (4.8 ± 1.8) and those with solitary kidney (11.0 ± 4.9) ($p = 0.235$) in our study. In addition, renal function seems to be better preserved following cryoablation than partial nephrectomy even in patients with solitary kidney. Turna et al. [14] demonstrated that the mean ΔeGFR for partial nephrectomy was 26% and that for cryoablation was 6%, with the difference being statistically significant.

There are some limitations in the present study. First, it has been well established that the GFR exhibits circadian variation (up to 30% over the 24-hr mean) [15]. Even though we took blood samples in the morning in all patients, day-to-day variations may have affected the data. Second, we could not provide a rational explanation for the finding that renal function improved in seven of 75 patients (9.3%) after cryoablation. Circadian variation or improvement of lifestyle habits, including adequate fluid intake after hospitalization, could have influenced this result. Third, we did not evaluate renal function over a year after cryoablation; however, preexisting nephropathy could have progressed and affected the eGFR results after 6 months [3]; thus, 6-month data would be appropriate to evaluate the impact of only cryoablation on renal function. Fourth, although our system showed high sensitivity and high NPV for predicting a worsening of CKD stage, the PPV was low. These results may limit the clinical utility of the mRN system. Fifth, because our patient sample was small, a study with a larger sample size is required.

In conclusion, the modified RENAL nephrometry (mRN) scoring system developed herein may be useful for predicting renal function after renal cryoablation.

Compliance with Ethical Standards

Conflict of interest The authors declare that they have no conflict of interest.

Ethical Approval All procedures performed in studies involving human participants were in accordance with the ethical standards of the institutional and/or national research committee and with the 1964 Declaration of Helsinki and its later amendments or comparable ethical standards. For this type of study formal consent is not required.

Informed Consent This study has obtained IRB approval from Kyushu University, and the need for informed consent was waived.

Consent for Publication For this type of study consent for publication is not required.

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