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FULL PAPER

Clinical observation and quality of life in terms of nasal sinusitis after radiotherapy for nasopharyngeal carcinoma: long-term results from different nasal irrigation techniques

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Objective: The aim of our study was to investigate the relationship between nasal irrigation techniques (NIT) and the survival rate and the quality of life (QOL) in patients with nasal sinusitis (NS).

Methods: We studied data from 1134 patients with nasopharyngeal carcinoma (NPC) who received radical radiotherapy, which were randomly divided into three groups (A, B and C). Group A used nasal irrigator; Group B used homemade nasal irrigation (NI) connector combined with enenator; and Group C used nasal sprayer. The clinical effects, 5-year overall survival (OS) and progression-free survival (PFS) were observed. Furthermore, the QOL in patients with NS was evaluated using the Sino-Nasal Outcome Test 20.

Results: The median follow-up time was 69 months. The 5-year OS and PFS were 80.5% and 73.2%,

respectively, for all patients. There was no significant difference in OS, PFS, xerostomia and neck skin toxicity grade 3 and greater among groups. There was no difference among groups. The incidence of NS was the highest in group C.

Conclusion: The symptoms of NS seriously affected the QOL period of 1 year. Group C showed no improvement during the follow-up period, which for A and B, by contrast, had after 1 year. Although the exact mechanism remains to be explored in NIT, our findings suggest that patients with NPC should nasal irrigate for 2 years after radiotherapy.

Advances in knowledge: Our study shows that a nasal irrigator is necessary for patients with NPC for a high QOL in terms of NS.

Southern China and Southeast Asia are endemic for nasopharyngeal carcinoma (NPC).¹ The local control rate is increased to approximately 95% in patients with locally advanced NPC receiving radiotherapy combined with chemotherapy.^{2,3} The survival was increased.⁴ The 5-year overall survival (OS) rate of locally advanced patients treated with two-dimensional conformal radiation therapy (CRT) alone was about 66%–70%.⁵ The 10-year survival rates were 98% and 60%, respectively, in patients with Stages I and II NPC after receiving radiotherapy alone.⁶ Although the survival rate is significantly increased, the incidence of odynophagia, difficulty in opening mouth, xerostomia, stuffy nose and other symptoms is high after radiotherapy.^{6,7} Nasal sinusitis (NS) occurs, frequently after radiotherapy, and often results in stuffy nose, dry nose and other symptoms, which seriously reduce the long-term quality of life (QOL) of patients with NPC. The occurrence of NS after radiotherapy in patients with NPC has been rarely reported, and systematic research and follow-up are absent. In this study, patients with NPC who received radiotherapy and were intervened with different nasal

irrigation techniques (NIT) were followed up long term. The QOL was evaluated using the Sino-Nasal Outcome Test 20 (SNOT-20), and clinical quantitative indicators were recorded. The aim was to improve the long-term QOL of patients with NPC by clinical intervention.

METHODS AND MATERIALS

General clinical data

From June 2005 to December 2010, 1289 patients were newly diagnosed with NPC in our hospital (Fuzhou General Hospital of Nanjing Command, Fuzhou, China), with confirmation by MRI of nasopharynx and neck and biopsy using nasopharyngeal fibroscope. Of them, 84 patients developed distant metastasis, 26 had a history of malignancy, 32 discontinued the treatment and 13 had incomplete imaging or clinical data. 1134 of them completed radical radiotherapy or chemoradiotherapy and were enrolled in this study, including 826 males and 308 females, with a median age of 48 years (12–84 years). According to the pathological classification of the World Health Organization, 1086 patients developed non-keratinizing, undifferentiated carcinoma (95.8%); 42

developed non-keratinizing, differentiated carcinoma (3.7%); and 6 developed keratinizing squamous carcinoma (0.5%). Subjects were randomly divided into groups A, B and C using a random number table. Clinical data and questionnaire results collected from each group are shown in Table 1.

Radiotherapy

316 patients were treated with conformal radiotherapy (2.0 Gy per fraction) with 6-MV X-ray beam. The patients were fixed with a plastic cushion and mask, and the low melting-point block was used. The primary tumours of NPC and the upper neck were mainly treated with a combined face-neck field and a posterior neck electron field. The lower neck was treated with a single anterior field (tangential field). A dose of 70 Gy was administered to primary nasopharyngeal tumours, and 64 Gy to metastatic cervical lymph nodes. A dose of 50 Gy was administered for prophylactic irradiation. 818 patients were treated with intensity-modulated radiotherapy (IMRT). Of them, 32, 129, 338, and 319 patients had NPC Stages I, II, III and IV, respectively. A total dose of 66.00–69.75 Gy (30–31 fractions) was prescribed for gross tumour volume of the primary tumour; 60.00–66.65 Gy (30–31 fractions) for the high-risk clinical target volume; and 54.0–55.8 Gy (30–31 fractions) for the low-risk clinical target volume.⁸

Chemotherapy

Of the total group, 162 patients received radiotherapy only. Of them, 41, 56, 43 and 29 patients were at Stages I, II, III and IV, respectively. In addition, 972 patients (85.7%) received chemoradiotherapy. Of them, 287 patients received neoadjuvant chemotherapy, of which 32, 249 and 6 patients completed 1, 2 and 3 cycles of neoadjuvant chemotherapy, respectively. Meanwhile, 78, 871 and 23 patients completed 1, 2 and 3 cycles of concurrent chemotherapy, respectively. The neoadjuvant chemotherapy and

concurrent chemotherapy regimens included a PC regimen (paclitaxel on Days 1–3 to a total dose of 135 mg m⁻², plus 80 mg m⁻² of cisplatin on Day 1, repeated every 21 days) and a cisplatin, fluorouracil (CF) regimen (cisplatin on Days 1–3 to a total dose of 80 mg m⁻², plus fluorouracil on Days 1–5 to a total dose of 750 mg m⁻², repeated every 21 days). Of the total group, 972 patients received 1–4 cycles of the PC chemotherapy regimen after radiotherapy.

Nasal irrigation

Group A: a disposable nasal irrigator was used. Specific procedures are as follows: connect the power, 100 ml of normal saline at approximately 37°C was infused into the capacity cup and the spray connector was inserted into the nostrils. A homemade nasal irrigation connector combined with an enemaator was used for Group B. Specific procedures are as follows: the patient was sitting with his/her head slightly forward. 500 ml of normal saline at approximately 37°C was infused into the water bag of the enemaator. The output end of the catheter was connected to a nasal irrigation connector (patent number: 201320207924.X). The bottom of the water bag was kept at a level higher than the head of the patient. The irrigation connector was inserted into the nasal vestibule and the nostrils were closed. The regulator of the catheter was turned on. The patient was instructed to have mouth breathing. The left and right nasal cavities were irrigated alternately. Group C: a nasal sprayer was used. Specific procedures are as follows: 100 ml of normal saline at approximately 37°C was infused into the capacity cup, the spray connector was inserted into the nostrils, using one hand squeeze the rubber ball with proper strength. Two irrigations were performed daily until 2 years after the last radiotherapy. If nasal bleeding occurred, do not irrigate the nasal cavity until it stops bleeding. Usually nasal cavity bleeding can cease spontaneously.

Table 1. Clinical data and questionnaire results of 1134 patients with nasopharyngeal carcinoma

Item	Group A	Group B	Group C	λ^2 value	<i>p</i> -value
Age (years)				0.02	0.89
Median	43	51	49		
Range	13–82	12–81	13–84		
Gender				2.04	0.36
Male	268	273	285		
Female	110	105	93		
TNM staging				2.85	0.24
Stages I and II	118	139	123		
Stages III and IV	260	239	255		
Radiotherapy				3.04	0.21
Conventional radiotherapy	97	112	107		
Static intensity-modulated radiotherapy	271	246	301		
Chemotherapy				8.09	0.06
No chemotherapy	43	67	52		
Neoadjuvant + concurrent + adjuvant	98	83	106		
Concurrent + adjuvant	237	228	220		

Efficacy assessment

Acute mucositis assessment: according to the Radiation Therapy Oncology Group radiation morbidity scoring criteria, mucositis was graded into four levels as follows: grade 0—no significant changes; grade 1—erythema of oral mucosa, obvious congestion, oedema and slight pain; grade 2—spotted ulceration of oral mucosa, requires soft diet only; grade 3—obvious ulceration of oral mucosa, requires liquid diet only; grade 4—oral alimentation not possible, mouth ulcers with purulent secretions.

Quality of life assessment

Patients were scored for QOL using the SNOT-20.⁹ The SNOT-20 includes 20 items covering four domains, that is, nasal cavity symptoms, sinusitis-related symptoms, sleep disorders and affective disorders. Each item is scored from 0 to 3 and yields a total score ranging from 0 to 100. The higher the score, the more severe the symptoms. Questionnaires were completed at five time points: before treatment (baseline), 6 months after treatment (time a), 1 year after treatment (time b), 2 years after treatment (time c) and 3 years after treatment (time d). All questionnaires were jointly completed by the doctor and patient. The data of a patient would be excluded if none of the items of any domain were scored. If only part of the items were answered, the domain scores were calculated by averaging the non-missing scores for individual questions within a domain. A patient would drop out if imaging evaluation data were absent or local recurrence or distant metastasis happened during the follow-up.

Follow-up

Subjects were asked to attend follow-up appointments every 3 months within the first 2 years after treatment, every 6 months 2–5 years after treatment and once a year 5 years after treatment. Follow-up procedures included head and neck MRI, nasopharyngoscopy, chest radiography and abdominal colour Doppler ultrasound. Bone scan was performed once every year.

Statistical analysis

SPSS® v. 13.0 (IBM Corporation, Armonk, NY) was employed for statistical analysis. Clinical data were presented as mean $\pm$ standard deviation. QOL domain scores were presented as mean values. Normality tests were performed using the χ^2 test. Comparison between groups was performed using the λ^2 test. Ranked data were analysed using the Kruskal–Wallis H -test. The Kaplan–Meier method was used to calculate survival rates and the log-rank method was used to test for the significance of differences. A p -value <0.05 was considered statistically significant.

RESULTS

Follow-up and survival rates

In the total group, the 3-year and 5-year follow-up rates were 96.2% ($n = 1090$ patients) and 86.7% ($n = 983$ patients), respectively, with a median follow-up of 69 months (3–92 months). 7.8% ($n = 89$) of patients developed nasopharyngeal recurrence, 3.2% ($n = 36$) developed cervical lymph node recurrence and 15.8% ($n = 179$) developed distant metastasis; and a total of 218 patients died. In all 1134 patients, the 5-year OS and progression-free survival (PFS) were 80.5% and 73.2%, respectively. The OS and PFS in each group are shown in Figures 1 and 2.

Figure 1. 5-year overall survival curves for each group.

Figure 2. 5-year progression-free survival curves for each group.

Acute radiation toxicities

Major acute toxicities included xerostomia, mucositis and neck skin toxicity in all subjects.

The incidences of Grade 0, 1, 2, 3 and 4 xerostomia were 3.3%, 41.9%, 54.8%, 0% and 0%, respectively. The incidences of Grade 0, 1, 2, 3 and 4 mucositis were 0%, 19.3%, 48.6%, 31.8% and 0.3%, respectively. The incidences of Grade 0, 1, 2, 3 and 4 neck skin toxicity were 0%, 31.1%, 57.9%, 8.7% and 2.3%, respectively. Acute toxicities in each group are shown in Table 2. Significant differences were found in neck skin toxicity among three groups ($p < 0.05$). In addition, significant differences were found between Groups A and C in mucositis ($p < 0.05$).

Between the IMRT group and the CRT group, significant differences were found only in mucositis ($p < 0.05$); however, there was no difference between the xerostomia and neck skin toxicity ($p > 0.05$). Acute toxicities of two groups are shown in Table 3.

Incidence of nasal sinusitis

In the total group, the incidences of NS at baseline, time a, time b, time c and time d were 42.6%, 56.3%, 86.1%, 75.8% and 69.7%, respectively. The incidence of NS was significantly different among three groups at baseline, time b and time d. The incidences in each group are shown in Table 2.

In the IMRT group, the incidences of NS at baseline, time a, time b, time c and time d were 43.0%, 55.9%, 71.1%, 57.4% and 71.5%, respectively. The incidences were 40.0%, 57.7%, 82.1%, 42.4% and 54.4% in the CRT group, respectively, there were

differences at time b, time c and time d ($p < 0.05$). The incidences in each group are shown in Table 3.

Quality of life assessment

Complete questionnaires were collected from 1134 (100%), 1106 (97.5%), 1005 (88.6%), 864 (76.1%) and 616 (54.3%) patients at baseline, time a, time b, time c and time d, respectively. The number of patients completing the questionnaire in each group is shown in Table 2. The SNOT-20 domain scores are shown in Table 4.

DISCUSSION

Compared with conventional radiotherapy, IMRT significantly improves the target dose coverage, increases the tumour tissue dose and provides survival benefits for patients with NPC.¹⁰ Su *et al*¹¹ reported that the 5-year PFS and OS were 77.0% and 83.5%, respectively, in 866 patients with NPC. In the present study, the 5-year PFS and OS were 73.2% and 80.5%, respectively, which were affected by the slightly large proportion of patients at advanced Stages III–IV (accounting for 66.5%). Concurrent chemotherapy still cannot significantly reduce the rate of distant metastasis, which may be owing to the limited capability of eliminating subclinical metastases resulting from the low intensity of chemotherapy.¹² In the present study, 85.7% of patients received concurrent radiotherapy, and 95.8% of patients developed non-keratinizing undifferentiated carcinoma for all patients. Both the PC and CF regimens were proven¹³ to be able to provide a survival rate higher than those previously reported.¹⁴ This result further confirmed that IMRT-combined induction chemotherapy and/or

Table 2. Incidence of acute toxicities in each group

Item	Group A	Group B	Group C	λ^2 value	<i>p</i> -value
Xerostomia				0.836	0.658
Grade 0	10	15	13		
Grade 1	161	162	152		
Grade 2	207	201	213		
Grade 3	0	0	0		
Grade 4	0	0	0		
Mucositis				4.959	0.084
Grade 0	0	0	0		
Grade 1	80	69	70 ^a		
Grade 2	191	191	169 ^a		
Grade 3	106	117	138 ^a		
Grade 4	1	1	1 ^a		
Neck skin toxicity				5.811	0.055
Grade 0	0	0	0 ^{a,b}		
Grade 1	106	112	134 ^{a,b}		
Grade 2	231	217	209 ^{a,b}		
Grade 3	31	40	28 ^{a,b}		
Grade 4	10	9	7 ^{a,b}		
Incidence of nasal sinusitis at each time point					
Baseline	179 (378)	158 (378)	136 (378) ^a	10.060	0.007
Time a	212 (372)	198 (365)	213 (369)	1.000	0.606
Time b	216 (336)	227 (317) ^a	301 (352) ^{a,b}	41.690	0.000
Time c	138 (283)	154 (274)	175 (307) ^a	4.770	0.092
Time d	112 (206)	161 (197) ^a	156 (213) ^{a,b}	37.630	0.000

The numbers enclosed by parentheses indicate the total number of questionnaires completed.

^aSignificant difference from Group A.

^bSignificant difference from Group B.

concurrent chemotherapy and/or adjuvant chemotherapy could improve survival. However, PFS and OS were similar using different NIT.

High doses of radiotherapy can improve survival but produce greater side effects.^{15,16} Lee et al¹⁷ reported that the incidences of Grade 1 and 2 xerostomia were 35% and 65%, respectively, 3 months after IMRT, and 50% and 0%, respectively, 12 months after IMRT. In the present study, the overall incidences of Grade 1 and 2 xerostomia were 41.9% and 54.7%, respectively, after radiotherapy. This result is similar to the findings of Lee et al.¹⁷ It is thus conjectured that xerostomia may not be eliminated within 3 months after radiotherapy. The incidence of Grade 1 xerostomia was 42.6%, 42.9% and 40.2% in Groups A, B and C, respectively; and the incidence of Grade 2 xerostomia was 54.8%, 53.2% and 56.3% in Groups A, B and C, respectively. No difference was found between the three groups ($p > 0.05$), indicating that nasal irrigation did not affect the extent of damage to the salivary glands. The incidences of oropharyngeal mucositis of $\geq$ Grade 2 was 78.8%, 81.7% and 81.5% in Groups A, B

and C, respectively, which were higher than the 73.7% incidence reported by Su et al.¹⁸ This is probably because most of the subjects enrolled in the study of Su et al¹⁸ had T1 or T2 carcinoma, whereas the majority of patients in the present study were at the middle and advanced stages, and a high proportion of these patients received chemotherapy. The use of disposable nasal irrigator could reduce the severity of oropharyngeal mucositis. The difference in skin damage between Groups C and Groups A and B might be associated with the poor compliance in skin protection during radiotherapy in Group C. However, the incidence of skin damage was 11.1%, 13.0% and 9.3%, respectively, in Groups A, B and C, which was similar to a previous finding (12.1%).¹⁹ The higher incidence found in Group B than in Group A might be associated with the difference in stage distribution. IMRT allows the delivery of a very high dose to the tumour target, while sparing the surrounding critical structures. The most acute toxicity during IMRT was mainly Grades 1 or 2, only a few cases of Grade 3 toxicity or worse acute toxicity were observed. Advanced toxicity developed because of chemotherapy, instead of IMRT alone.¹⁸ However, our results have indicated that IMRT-

Table 3. Incidence of acute toxicities between the intensity-modulated radiotherapy (IMRT) and CRT

Item	IMRT	CRT	λ^2 value	<i>p</i> -value
Xerostomia			9.000	0.003 ^a
Grade 0	31	7		
Grade 1	361	114		
Grade 2	426	195		
Grade 3	0	0		
Grade 4	0	0		
Mucositis			113.950	0.000 ^a
Grade 0	0	0		
Grade 1	158	61		
Grade 2	503	48		
Grade 3	157	204		
Grade 4	0	3		
Neck skin toxicity			0.294	0.588
Grade 0	0	0		
Grade 1	265	87		
Grade 2	496	201		
Grade 3	88	11		
Grade 4	9	17		
Incidence of nasal sinusitis at each time point				
Baseline	352 (818)	121 (316)	2.107	0.147
Time a	451 (806)	172 (298)	0.275	0.600
Time b	528 (742)	216 (263)	12.155	0.000 ^a
Time c	386 (673)	81 (191)	13.383	0.000 ^a
Time d	392 (548)	37 (68)	8.388	0.004 ^a

The numbers enclosed by parentheses indicate the total number of questionnaires completed.

^a*p* < 0.05 for comparison between the IMRT and CRT groups.

related toxicity was accepted. Efforts to reduce incidence of sinusitis was a priority. However, the incidence in IMRT groups was higher than in CRT groups after 1 year (57.4% *vs* 42.4% and 71.5% *vs* 54.4%). The difference in amount between the groups could be the biggest influenced factor. Meanwhile, the chemotherapy could be a potential risk factor to increase the incidence of sinusitis. In our study, 972 patients (85.7%) received chemoradiotherapy, which could increase the short- or long-term sinusitis.

Most of the recent studies on NPC only focused on therapy selection and median follow-up, but detailed analysis of side effects of radiotherapy, including NS, has not been reported.²⁰ Although many precipitating factors have been identified for NS, the core of its physiological pathology is ostium stenosis or obstruction, and mucus and mucociliary clearance disorders.²¹ Radiotherapy can directly damage ciliated cells on the sinus mucosal surface, which will manifest as acute inflammation in the early stage and as irreversible mucosal atrophy and distortion in the late stage.²² It has been demonstrated that endoscopic

clearance of factors that block sinus drainage can significantly reduce symptoms of sinusitis after radiotherapy.²³ This also confirms that nasal ventilation and drainage disorders caused by radiation are the basis of the pathogenesis of NS. Long-term nasal irrigation during and after radiotherapy helps to reduce the incidence of sinusitis. In this study, the incidence of sinusitis peaked at 86.1% 1 year after radiotherapy, which is consistent with a previous finding.²⁴ The higher incidence found in Group C than in Group A at baseline might be associated with the larger proportion of T3 and T4 patients in Group A. All the three groups received long-term nasal irrigation, and no differences were found 6 months after radiotherapy. However, the incidence was significantly lower in Group A than in Groups B and C within 3 years of follow-up after radiotherapy, especially at 1 year and 3 years of follow-up. This result proved the advantage of using the nasal irrigator over other techniques. The nasal sprayer did not prove its advantages during long-term use. The longer the follow-up, the higher the incidence. This may be related to insufficient momentum that leads to the inability to ensure opening of the ostium. The

Table 4. Sino-Nasal Outcome Test 20 scores at each time point

Item	Group	Baseline, mean (quartiles)	Time a, mean (quartiles)	Time b, mean (quartiles)	Time c, mean (quartiles)	Time d, mean (quartiles)
Nasal cavity symptoms	A	94 (90; 100; 100)	84 (76; 90; 100)	88 (90; 100; 100)	90 (90; 100; 100)	91 (90; 100; 100)
	B	92 (89; 100; 100)	81 (68; 86; 98)	93 (92; 95; 100)	90 (90; 96; 100)	87 (86; 98; 100)
	C	88 (88; 96; 100)	79 (66; 81; 98)	86 (83; 92; 98)	87 (85; 96; 98)	90 (90; 94; 96)
Nasal sinusitis symptoms	A	82 (71; 83; 86)	76 (61; 72; 83)	48 (42; 56; 61)^a	78 (72; 80; 89)	80 (76; 86; 96) ^a
	B	86 (75; 85; 89)	79 (66; 76; 85)	52 (48; 63; 70)^a	80 (62; 84; 96)	82 (73; 85; 100) ^a
	C	85 (69; 83; 87)	72 (65; 73; 81)	36 (32; 48; 58)^a	76 (56; 80; 95)	73 (58; 75; 90)^a
Sleep disorders	A	96 (96; 100; 100)	92 (88; 94; 98)	88 (82; 88; 92)	90 (85; 92; 96)	93 (87; 91; 96)
	B	94 (94; 100; 100)	92 (92; 96; 98)	86 (85; 89; 94)	93 (86; 92; 96)	92 (91; 96; 98)
	C	96 (94; 98; 100)	94 (92; 96; 100)	88 (80; 86; 90)	92 (82; 88; 93)	92 (92; 95; 98)
Affective disorders	A	94 (92; 96; 100)	89 (81; 92; 96)	83 (79; 85; 90)^a	88 (81; 90; 93)	88 (83; 92; 96)
	B	92 (88; 96; 98)	87 (83; 91; 96)	81 (76; 83; 91)^a	89 (83; 89; 92)	90 (86; 90; 95)
	C	92 (90; 94; 100)	87 (81; 93; 97)	73 (68; 81; 92)^a	87 (79; 86; 90)	86 (84; 89; 93)

Bold indicates significant difference from baseline.

^a $p < 0.05$ for comparison between volume subgroups; quartiles = 25th; 50th; and 70th percentiles.

homemade nasal irrigation connector produced only modest effects, but it can be promoted at the grassroots level because of its low cost and portability.

Reduced QOL caused by side effects of radiotherapy for NPC has been intensively investigated in recent years.^{25,26} Mucosal inflammation is considered to be one of the most intolerant adverse reactions of radiotherapy.²⁷ However, long-term follow-up of reduced QOL caused by NS after radiotherapy has not been reported. The research on QOL is affected by various factors, such as treatment modalities. Therefore, only a single symptom, NS, was specifically followed up using SNOT-20 to reduce potential errors in this study. The subjects had the most severe nasal cavity symptoms within 6 months after radiotherapy, but the symptoms were eliminated in most subjects within the follow-up period. In terms of the NS scores, QOL was seriously affected within 1 year after radiotherapy, especially in the nasal sprayer group, which was associated with the incidence of NS. However, small fluctuations were observed in the scores of sleep and affective disorders within 1 year after radiotherapy.

Because of the differences in emotions resulting from the nasal cavity and NS symptoms, the nasal irrigator group showed a better QOL than the other two groups, and the nasal sprayer group reported the worst QOL.

CONCLUSIONS

Different NIT had no significant effect on OS and PFS of patients with NPC. The highest incidence of NS was recorded at 1 year of follow-up after radiotherapy. Moreover, nasal symptoms seriously reduced the QOL of patients with NPC at 6 months and 1 year of follow-up. The patients using the nasal sprayer had the lowest QOL in the 3 years of follow-up. Long-term nasal irrigation with the nasal irrigator can improve the QOL of patients with NPC after radiotherapy; and the use of a homemade nasal irrigator can be promoted at the grassroots level for its convenience and low cost.

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