



The effectiveness of the follow-up of patients after surgery due to cancer of the head and neck

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Aim: The aim of this study was to assess the effectiveness of the follow-up (FU) of patients after head and neck cancer treatment. **Materials & methods:** This is a retrospective cross-sectional study and concerns the analysis of outpatient records of 85 women and 355 men who reported at FU visits between 2011 and 2016 in ENT Department in the University Of Medical Sciences in Poznan, Poland. **Results:** The value of the FU scheme was confirmed by a high rate of recurrence detected in a medical examination (60%) and routine imaging studies (27%), as opposed to only 13% in spontaneous reports. **Conclusion:** The FU therapeutic profit in the form of high percentages of preclinical relapse at a reasonable cost is justified medically and socially.

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Follow-up (FU) is a standard procedure in patients after oncological surgery. The main aim of FU schemes is to detect possible recurrence in an early stage, thereby increasing the percentage of cure. Another FU task is to assess the effectiveness of treatment, early diagnosis, treatment of complications, ensure permanent contact with an oncology team familiar with the history of the patient's disease and to provide psychological care [1–4]. In the FU process, the oncology team uses various techniques, such as clinical evaluation, endoscopy, imaging tests, blood tests and markers. It is important to optimize the frequency and number of ordered tests and visits, in order to ensure the best possible patient care, while rationalizing costs.

However, in the literature, there is no consent as to the superiority of one over the other FU protocol [4–6]. Programs that monitor patients suffering from head and neck cancer vary in different centers. The differences include: the duration of the FU, frequency of visits, recommended imaging and laboratory tests, patient education and recommended rehabilitation [7,8]. In practice, visits often take place on an individual basis and depend on the experience of the particular center [9].

The main aim of FU visits is to detect potential 'silent' recurrence at the earliest possible stage. Because the majority of relapses occur within the first 2 years after treatment, all guidelines found in the literature emphasize the need of more frequent visits in the aforementioned period of time. Depending on their own experiences, some authors propose shortening of the period of intensive visits only to the first year [7], others to the first 2 years [4,10], rarely to 3 years as in the case of SFORL (La Société Française d'Oto-Rhino-Laryngology, Paris, France) (Table 1) [11]. After this period, the interval between visits gradually increases.

In the questionnaire sent to the members of British Association of Head and Neck oncologists (BAHNO), Joshi *et al.* [4] asked about the frequency of FU visits for their patients. The answers given by doctors of various specialties (otolaryngologists, oncologists, surgeons and maxillofacial and plastic surgeons) were comparable. The median for visits during the first year was one visit every 4 weeks, in the second year one every 2 months, in the third year one every 3–6 months, and in the fourth and fifth years one every 6 months. Over 5 years, 39% of oncology teams saw their patients every year, and 12% ended FU at this point [4]. The authors of FU programs agree that a

Table 1. Cumulative recurrence rates (%) in the years after surgery due to cancer of the head and neck.

Study (year)	Year of follow-up					Ref.
	1st year	2nd year	3rd year	4th year	5th year	
Jung <i>et al.</i> (2014)	26.7	40.6	52.5	59.4	60.4	[9]
Haas <i>et al.</i> (2001)	–	70	–	–	–	[2]
Kothari <i>et al.</i> (2010) [†]	56	70	85	–	–	[7]
Pagh <i>et al.</i>	31	55	69	83	86	[12]
Sullivan BP <i>et al.</i>	19.1	24.1	–	–	–	[13]

[†]Suspicion of recurrence.

Table 2. Frequency and duration of follow-up by selected authors and associations.

Study (year)	Interval between visits (in months) taking into account the passage of time from the recovery						Ref.
	1st year	2nd year	3rd year	4th year	5th year	Next years	
NCCN (2015)	1–3	2–6	4–8	4–8	4–8	12	–
BAHNO (2011)	< 2	< 2	3–6	3–6	3–6	Patient discharged. Elongation in some cases	–
Department of Otolaryngology and ENT Oncology in Poznań	1	2	3	3	3	12	–
SFORL Halimi <i>et al.</i> (2015)	2	3	4	6	6	Six patients with a positive history of alcohol and nicotine addiction	–
DAHANCA Pagh <i>et al.</i> (2013)	3	4	6	6	12	12	[12]
Flynn <i>et al.</i> (2010)	3	4	6	6	6	–	[15]
Haas <i>et al.</i> (2001)	1	2	3	4	4	12	[2]
Gellrich <i>et al.</i> (2002)	1	2.5	4	12	12	–	[14]

BAHNO: British Association of Head and Neck Oncologist; DAHANCA: Danish Head and Neck Cancer Group; NCCN: National Comprehensive Cancer Network; SFORL: La Société Française d'Oto-Rhino-Laryngologie.

minimum FU should last 5 years (Table 2.). The differences relate to the period that follows these 5 years. National Comprehensive Cancer Network, DAHANCA and our center in the University Of Medical Sciences in Poznan, Poland, recommend lifelong patient monitoring once a year. Others, like BAHNO recommend a discharge of the patient from FU and in certain cases (not included in the recommendations) the extension of this period. SFORL is more specific on this subject and recommends life-long monitoring of patients every 6 months in the case of a positive history of nicotine and alcohol addiction. Some centers discharge the patient from further FU after 5 years [12,13].

The purpose of this paper is to evaluate the efficiency of monitoring patients treated for head and neck cancers in a single tertiary reference center, Department of Otolaryngology and Head and Neck Oncology at the University Of Medical Sciences in Poznan, Poland and compare the results with the data available in the literature. The ultimate goal is to improve and modify the FU guidelines, which may affect the efficiency, such as the improvement of reportability and higher detection of failures.

Materials & methods

The ENT outpatient clinic of the Department of Otolaryngology and ENT Oncology in the University Of Medical Sciences in Poznan, Poland, admits about 3000 cancer patients per year. This study is a retrospective cross-sectional study and concerns the analysis of outpatient records of all patients who reported at FU visits in 2011. The study group consisted of 85 women and 355 men. Inclusion criteria were as follows: patients after surgery with or without adjuvant radiotherapy/chemotherapy, who reported to the outpatient clinic at least three-times per year within 2 years. The group was analyzed from the first visit after the surgery, until the last visit in 2011, in terms of distribution of the frequency of visits in particular subgroups of patients (age, sex, place of residence and primary focus) (Table 3).

The most common scheme of FU visits includes a physical examination in the first year once a month; in the second year every 2 months, and in the 3–5 years on a quarterly basis; ultrasonographic evaluation of the neck, panendoscopy and radiological examination of the chest once a year. The valuation of the follow-up by the Polish

Table 3. Characteristics of the study group of patients.

Ordinal number	Variable	Category	n	%
1.	Gender	Woman	83	18.9%
		Man	355	81.1%
2.	Age	Under 50 years	29	6.6%
		50–59 years	140	32.0%
		60–69 years	194	44.3%
		70 years and more	73	16.7%
		No data available	2	0.5%
		M (SD) Min–max	61.3 (9.3)	29–85
3.	The size of the place of residence (population)	Less than 1000	59	13.5%
		1000–5000	85	19.4%
		5001–25,000	111	25.3%
		25,001 – 50,000	41	9.4%
		Above 50,000	120	27.4%
		No data available	22	5.0%
4.	The location of the primary tumor	Larynx	305	69.6%
		Oral cavity	64	14.6%
		Middle pharynx	25	5.7%
		Salivary glands	24	5.5%
		Nasal cavity/maxillo-ethmoid massif	13	3.0%
		Nasal part of the pharynx	3	0.7%
		CUP	3	0.7%
		Lower pharynx	1	0.2%
5.	The number of years under medical supervision	Up to 2 years	150	34.2%
		From 2 to 5 years	118	26.9%
		Above 5 years	170	38.8%
		M (SD) Min–max	5.1 (4.2): 1–27	
Total			438	100.0%
CUP: Cancer of unknown primary; M: Mean; SD: Standard deviation.				

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National Insurance varies from €12 (a specialist examination alone) to €22 (extra ultrasound and endoscopy). Imaging studies cost between €75 (CT) and €120 (MRI).

The most important end point was the comparison of the number of recurrences detected during a routine examination versus spontaneous reports. In addition, the following relationships were evaluated: the number of relapses as: the number of held FU visits, the number of imaging tests ordered, time to recurrence, the number of failures detected in various time intervals after completion of treatment: >2 years, 2–5 years and <5 years, the type of treatment failure. Another end point was the way of FU realization assessing friendliness, and indirectly the feasibility of this regimen for patients: frequency of reports depending on the age, sex, place of residence, location of the primary lesion and the percentage of visits that ended with medical advice.

The statistical analysis was performed using Statistica 10.0 (StatSoft Inc., 2011, Krakow, Poland). The results for variables on the qualitative scales are presented as frequency tables, together with percentages. In the case of quantitative variables, basic measures of descriptive statistics were calculated: arithmetic mean, median, quartiles and standard deviation. The compliance of distribution of variables with normal distribution was studied using the Shapiro–Wilk test. Since the distributions of all variables differed significantly from the normal distribution, nonparametric methods were used to verify hypotheses. The intergroup comparisons used the U Mann–Whitney test (for two peer groups), ANOVA rank Kruskal–Wallis test with *post hoc* Dunn test (for more than two groups). Wilcoxon matched-pairs test was applied to compare parameter values measured at three-time intervals. Correlation analysis was performed using Spearman's rank correlation coefficient and χ^2 test. It was assumed that the significance level is $\alpha = 0.05$. When the calculated probability was $p < 0.05$, results were considered to be statistically significant.

Table 4. Recurrence in time intervals for each primary lesion.

Primary tumor	Recurrence in time intervals							
	Up to 2 years		2–5 years		>5 years		Total	
	n	%	n	%	n	%	n	%
Larynx	24	75%	6	67%	8	61.5%	38	70.3%
Oral cavity	4	12.5%	2	22%	0	0%	6	11.1%
Central pharynx	0	0%	0	0%	0	0%	0	0%
Lower pharynx	0	0%	0	0%	0	0%	0	0%
Nasal cavity/maxillo-ethmoid massif	3	9.4%	0	0%	1	7.7%	4	7.4%
Nasal part of the pharynx	0	0%	0	0%	1	7.7%	1	1.9%
CUP	0	0%	1	11%	0	0%	1	1.9%
Salivary glands	1	3.1%	0	0%	3	23.1%	4	7.4%
Total	32	100%	9	100%	13	100%	54	100%

CUP: Cancer of unknown primary.

All procedures performed were in accordance with the ethical standards of the institutional research committee, Bioethics Committee of the University Of Medical Sciences in Poznan, Poland and with the 1964 Helsinki declaration and its later amendments or comparable ethical standards. The research did not include clinical trials.

Results

The occurrence of relapse

Statistical analysis of the data allowed us to determine the following relationships: is cancer significantly more frequently detected during routine visits or spontaneous reports? Was treatment failure significantly more often detected in the specified time interval for each primary lesion and types of recurrence?

Treatment failure occurred in 54 out of 438 patients (12.3%), including 36 (66.7%) local recurrence, ten (18.5%) nodal, seven (13.0%) distant and one (1.9%) multifocal. Time to treatment failure: 59.3% in 2 years of treatment, 16.7% in 2–5 years and 24.1% over 5 years. Treatment failures for each primary lesion at given intervals of time are shown in the Table 4.

Larynx cancer recurrences (n = 38; 63.1%), oral cancer recurrences (n = 6; 66.7%), nasal and maxillo-ethmoid massif cancer (n = 4; 75%) were most often detected in period of up to 2 years after treatment. Salivary gland cancer recurrences (n = 4; 75%) were most frequently detected in the period of more than 5 years after surgery.

The method of recurrence diagnosis

In the analyzed group, routine subjective medical check-up proved to be the most effective method in detection of the treatment failure (31/54 patients 57.4%); imaging studies detected 14 (25.9%) and self-report revealed only seven recurrences (13.0%). In the case of two patients we were unable to clearly classify them to any of the aforementioned groups.

The number of visits completed with the detection of recurrence versus the FU interval

In the whole group of patients and the entire analyzed period of 5 years, 8585 visits were conducted, during which 54 recurrences were detected, that is, one relapse per 159 visits. By FU period: <2 years: a total group of 150 patients underwent 3262 visits and 23 recurrences were detected, that is, one recurrence/142 visits; 3–5 years: a group of 118 patients underwent 1941 visits and found six recurrences, or one relapse/323.5 visits; >5 years: a group of 170 patients underwent 1138 visits and detected nine recurrences, or one relapse/126.4 visits.

Type of recurrence versus the period in which the relapse was detected

There were no statistically significant association between the time of treatment failure and the type of failure. Most recurrences were detected up to 2 years after surgery (n = 32; 59.3%), followed by a period of greater than 5 years (n = 13; 24.1%) and less in the period between 2 and 5 years (n = 9; 16.6%) (Table 5).

Table 5. Type of treatment failure and time when it was detected.

Type of recurrence	Recurrence in time intervals							
	Up to 2 years		2–5 years		<5 years		Total	
	n	%	n	%	n	%	n	%
Local	20	62.5%	6	66.7%	10	76.9%	36	66.7%
Nodal	8	25.0%	2	22.2%	0	0.0%	10	18.5%
Distant/multifocal	4	12.5%	1	11.1%	3	23.1%	8	14.8%
Total	32	100%	9	100%	13	100%	54	100%

The result of χ^2 test: $\chi^2 = 5.5$; df = 6; p = 0.4762.

Table 6. Type of treatment failure and the method of recurrence diagnosis.

Type of recurrence	By the patient		In the physical examination		In the imaging study		Total	
	n	%	n	%	n	%	n	%
Local	6	85.7%	25	80.6%	5	35.7%	36	69.2%
Nodal	0	0.0%	2	6.5%	8	57.1%	10	19.2%
Distant	1	14.3%	4	12.9%	1	7.1%	6	11.6%
Total	7	100%	31	100%	14	100%	52	100%

The result of χ^2 test: $\chi^2 = 17.9$; df = 6; p = 0.0065.

Type of recurrence & method of diagnosis

Local recurrence was significantly more frequently detected by self-report of the patient and examination performed by the oncology team, whereas imaging studies usually detected nodal recurrence. The result of the chi-square test was statistically significant (p = 0.0065; Table 6).

Analysis of epidemiological variables

The aim was to determine whether gender, age, place of residence, primary lesion and the occurrence of relapse influenced the number of FU visits with readmission to the department, the number of ordered imaging studies, respectively at intervals >2 years, 2–5 years and <5 years after surgery. In these cases, the statistical analysis used nonparametric methods, since all distributions deviated from normality, which were confirmed in the Shapiro–Wilk test.

Age

The correlation analysis used Spearman rank correlation coefficient R with the test of significance for this factor. There was no relationship between patients' age and the total number of FU visits, the number of imaging tests and rehospitalization.

Place of residence

The analysis was based on the frequency of FU visits at various intervals <2, 3–5 and >5 years and the number of imaging studies in relation to patients' place of residence. There was no relationship in any interval between the size of the town/village and the distance from the center conducting FU and the total number of visits, the number of visits completed with medical advice, the number of imaging tests and rehospitalization.

Sex

The results of U Mann–Whitney test indicate that there are statistically significant differences between groups concerning the total number of imaging studies and the total number of readmissions. The total number of imaging studies differed statistically significantly between sexes (p = 0.0017). The mean and median for men were 1.0 and 0, respectively, for women 1.7 and 1. The total number of readmissions differed statistically significantly between sexes (p = 0.0476) as well. The mean and median for men were 0.7 and 0, respectively, for women 1.0 and 0.

Discussion

Discussion of FU

FU of patients after surgery due to head and neck cancer is a complex process, which requires the involvement of both medical personnel and the patient. High frequency of visits, especially during the first 2–3 years after operation, can be overwhelming for the patient as shown in some studies. For example, the study conducted by Kothari *et al.* proved that as much as 73% of patients opted for less intense FU program [7]. Referring to our results, there were 30–40% fewer visits than in the recommended schedule. It was not influenced by the patients' age, sex or place of residence.

The role of FU in increasing overall survival rate is inconclusive. In the general population of patients with cancer of the head and neck region, most authors do not support thesis that increased intensity of the FU brings advantages [2,15,16]. Some authors, such as Haas *et al.* [2] propose to focus FU on the locoregional recurrences, because their research did not show that the detection of distant metastases, or secondary primary malignancy correlated with the increased survival of patients. Thereby, the authors sometimes suggest a more individualized FU scheme. Lester *et al.* postulates for the limitation of FU to 7 years for the larynx and 3 years for lower and middle pharynx. His findings were based on a study conducted in a group of 676 patients. In the studied group, 95% of recurrences after treatment of larynx cancer occurred within the first 4.7 years, and in patients suffering from cancer of the lower and middle pharynx 2.7 and 2.3 years, respectively [17].

Reportability

The problem of reportability is caused on the one hand by the type of implemented FU regimen and on the other patients' education and knowledge about alarming symptoms. Due to the low FU efficiency, Kothari *et al.* suggests that it might be necessary to educate patients and cooperate with healthcare professionals who are not doctors [7]. There is a clear need to educate patients on the benefits of quitting tobacco smoking or alcohol abuse [18,19], but also instructing them about the need to report if any disturbing symptoms appear.

The recommendations of SFORL and BAHNO imply that there is a need to inform patients about first symptoms that may indicate a recurrence of cancer, and what circumstances should prompt them to an earlier appointment with their oncology team [11]. The literature on the effectiveness of detection of recurrence by the patient differs from as much as 85% [3,12] to just 24.8 and 17.5% [9,14]. In a prospective study on the population of 1039 patients, Kothari *et al.* determined that the sensitivity of self-reporting was 98.1%, with a negative predictive value of 99.6% [7]. According to the authors, we should not overestimate self-reports. Our own material contained only 13% spontaneous reports with relapse as opposed to 60% of recurrences detected by a routine medical examination and 27% by imaging tests. There is no doubt that some of failures are noticed in the first place by the patient, but maybe he/she does not associate symptoms with a potential relapse. It is important to educate patients during and after treatment.

The FU scheme recommended and used in our department comprises of about 18 FU visits in the first 2 years, and 12 visits over the next 3 years. In the study material, up to 2 years after surgery, the mean number of FU visits was 12.7 and 7.2 in the period from 2 to 5 years after surgery. This shows that visits differ from the determined timetable; in the period up to 2 years there were approximately 30% (29.4%) fewer visits than it was recommended based on the schedule, and in the period from 2 to 5 years 40% less. Gellrich *et al.* [14] studied compliance with the recommendations in group of patients suffering from head and neck cancer [14]. In this prospective study based on a questionnaire, the authors assessed the FU in the perspective of early detection of recurrence, cost and efficiency of treatment in 144 patients after treatment of oral cancer who received a total of 9444 consultations. In this group of patients, no more than 50% came to FU visits according to the schedule, and only 11% attended on a regular basis in the FU within the first 3 years. The authors doubt that an intense FU scheme would meet with the acceptance of patients. In another multicenter study on a group of 1039 patients, 73% of them supported the idea of a less intensive FU program, while 84% of patients claimed that FU visits were too frequent [7]. In Denmark, where the FU system is centralized, the problem of compliance seems to be much less significant. In a prospective study of 619 patients, Pagh *et al.* [12] reported that only 11% of them did not report on the designated visits, but all of them attended skipped visits eventually. Only 1.5% of patients were not included in the FU program [12].

Discussion of detecting recurrence during routine versus spontaneous visits

The total number of recurrences in our group was 54. In case of 52 medical records we were able to indicate how the recurrence was detected. Most recurrences were detected in a medical examination – 31 (60%), followed by

routine imaging studies – (27%), and the least by the self-report (13%). It turns out that most recurrences detected by both the patient and the oncology team are local recurrences, while imaging studies detected mainly nodal relapse ($p = 0.0065$). If we sum up the number of recurrences detected by the patient to the number of recurrences detected in the course of FU, the FU effectiveness in terms of detection of new recurrence was 87%. This result is surprisingly high when compared with most of the published, available studies. Similar findings were published by Jung *et al.* In their retrospective work in the group of 520 patients after surgery, radiotherapy, chemotherapy or combined therapy, they assessed the recurrence rate detected by: the oncology team (53; 52.4%); by patients (25; 24.8%), and by routine imaging tests (23; 22.8%) [9]. In the study conducted by Agrawal *et al.* [3], 85% of patients reported new symptoms before the diagnosis of recurrence by the oncology team, even though in this group, 82% of patients complied with the recommendations of FU visits, and attended them regularly [3]. Based on medical records of 190 patients after treatment of head and neck cancer stage IIIrd and IVth, Flynn *et al.* [15] proved that in this group most recurrences were reported by the patient (63%) compared with 37% discovered by examination performed by the oncology team. In addition, there was no significant difference in the survival in these two groups of patients [15]. In a prospective cross-sectional study of 619 surgical and non-surgical patients, Pagh *et al.* [12] observed that even though 85% of recurrences were symptomatic, patients attended a routine check, not asking for an earlier visit. They estimated the risk of confirmed recurrence in the asymptomatic patient reporting at the FU at 1.3%. So, in order to detect a recurrence, 99 asymptomatic patients should be examined [12]. In the prospective multicenter study in 1039 patients, Kothari *et al.* found that only 0.3% of asymptomatic patients ($n = 3/1039$) had a suspicion of a recurrence, including only two confirmed cases (0.2%). The suspected recurrence occurred in 10% of patients who came for a routine visit (10%) and in 68% of patients who asked for consultations (60/88). In our material, up 2 years after surgery one treatment failure was found per 142 visits, in the period from 3 to 5 years it was one per 324 visits, and in the period of more than 5 years of surgery one per 126 visits.

Discussion of the number of visits, additional tests & the percentages of detected failures

In the course of FU, imaging studies are used in various clinical situations. In our department, we usually perform computed tomography, magnetic resonance, ultrasound and PET/PET-CT. Different studies are inconclusive in terms of sensitivity and specificity of aforementioned methods in the diagnosis of early recurrence. There is an important advantage of PET/PET-CT over other tests thanks to determination of the metabolic activity of the tumor, which is particularly useful when there is a doubt in 'conventional' examination. It is very effective in detecting primary tumor metastases of the unknown origin [20] for FU of tumors of the nasopharynx [21]; in the FU of nodal changes in different meta-analyses it ranks comparatively or better than CT, MRI or ultrasound [22,23]. The importance of this study certainly will increase due to the ever growing group of patients referred for primary radiotherapy and chemoradiotherapy [8]. The high negative predictive value of PET/PET-CT for suspected recurrence or residual changes allows these patients to avoid invasive operations, such as reconnaissance surgeries [21,24].

Conclusion

The FU scheme was followed according to the schedule by the majority of patients; 70% up to 2 years, 60% from 2 to 5 years. A place of residence had no impact on the frequency of visits and people from smaller towns benefited from the FU in the same degree.

The value of the FU scheme was confirmed by a high rate of recurrence detected in a medical examination (60%) and routine imaging studies (27%), as opposed to only 13% in spontaneous reports. Local recurrences were the most common in presented group and in most cases an effective initial diagnosis was made by a physical examination carried out by a specialist.

The method of FU with a high frequency of visits during the first 2 years is reasonable. One treatment failure was observed per 142 and 324 of the total number of visits in the ranges of <2 and 3–5 years, respectively.

The FU therapeutic profit in the form of high percentages of preclinical relapse and human benefit in the form of high percentages of FU visits ended with medical advice at reasonable cost is justified medically and socially. Reportability to FU visits should be intensified through patients' education during and immediately after treatment.

Financial & competing interests disclosure

The authors have no relevant affiliations or financial involvement with any organization or entity with a financial interest in or financial conflict with the subject matter or materials discussed in the manuscript. This includes employment, consultancies, honoraria, stock ownership or options, expert testimony, grants or patents received or pending, or royalties.

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Summary points

- The follow-up (FU) scheme was followed according to the schedule by the majority of patients.
- A place of residence had no impact on the frequency of visits and people from smaller towns benefited from the FU in the same degree.
- The value of the FU scheme was confirmed by a high rate of recurrence detected in a medical examination (60%) and routine imaging studies (27%), as opposed to only 13% in spontaneous reports.
- Local recurrences were the most common in presented group.
- In most cases an effective initial diagnosis was made by a physical examination carried out by a specialist.
- The method of FU with a high frequency of visits during the first two years is reasonable.
- In presented group, one treatment failure was observed per 142 and 324 of the total number of visits in the ranges of <2 and 3–5 years, respectively.
- Reportability to FU visits should be intensified through patients' education during and immediately after treatment.

Ethical conduct of research

The authors state that they have obtained appropriate institutional review board approval or have followed the principles outlined in the Declaration of Helsinki for all human or animal experimental investigations. In addition, for investigations involving human subjects, informed consent has been obtained from the participants involved.

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