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HEAD AND NECK

Italian validation of the Neck Dissection Impairment Index questionnaire

Validazione in italiano del questionario Neck Dissection Impairment Index

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SUMMARY

Objective. The Neck Dissection Impairment Index (NDII) questionnaire is a useful and validated Quality of Life (QoL) evaluation instrument in patients undergoing major head-neck surgery. Its English version has been used in several studies in the last years. The aim of this work is to validate the NDII in Italian for both patient assessment and future studies.

Materials and methods. Cross-cultural adaptation of the NDII was performed using standard techniques. Items of the original NDII were translated into Italian by a professional translator and two bilingual investigators. A final consensus version was obtained and given to two professional translators to produce a literal translation into English. The two translators and an expert committee synthesised the results of the translations in an English back-translated version that was compared with the original to check that they had the same semantic value.

Results. Finally, a total of 42 patients completed both copies of the translated questionnaires. Internal consistency proved to be excellent, with Cronbach's alpha = 0.95.

Conclusions. The NDII was successfully translated into Italian and its use was easy for patients. The translation of the NDII can represent a useful tool for individual patient assessment and future research.

KEY WORDS: quality of life, neck dissection, questionnaire, head and neck surgery, validation

RIASSUNTO

Obiettivi. *Lo scopo del lavoro è convalidare il questionario Neck Dissection Impairment Index (NDII) in italiano, unico questionario specifico per valutare in maniera specifica la qualità di vita dei pazienti sottoposti a svuotamento laterocervicale.*

Materiali e metodi. *L'adattamento interculturale dell'NDII è stato eseguito utilizzando tecniche standard. Gli elementi dell'NDII originale sono stati tradotti in italiano da un traduttore professionista e due investigatori bilingue. Una versione finale di consenso è stata ottenuta e data a due traduttori professionisti per produrre una traduzione letterale in inglese. I due traduttori e un comitato di esperti hanno sintetizzato i risultati delle traduzioni in una versione retrotradotta in inglese che è stata confrontata con l'originale per verificare che avessero lo stesso valore semantico. Infine, un totale di 42 pazienti ha completato entrambe le copie dei questionari tradotti.*

Risultati. *La consistenza interna si è rivelata ottima, con alfa di Cronbach = 0,95. L'NDII è stato tradotto con successo in italiano e il suo utilizzo è stato facile per i pazienti.*

Conclusioni. *La traduzione dell'NDII potrebbe rappresentare uno strumento molto utile per la valutazione del singolo paziente e la ricerca futura.*

PAROLE CHIAVE: *qualità di vita, svuotamento laterocervicale, questionario, chirurgia testa e collo, validazione*

Introduction

Carcinomas of the head and neck are estimated to be the 6th most common cancer worldwide, and metastatic spread to the lymph nodes is extremely fre-

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quent [1]. Therapeutic options for this disease are surgery and radio-chemotherapy, in several combinations. With regard to surgery, uni- or bilateral neck dissection (ND) is widely accepted as the gold standard treatment for neck nodes [2]. ND is not, however, free from medium- and long-term complications, such as XI, VII and XII cranial nerve deficit and aesthetic burden of the surgical scar [3]. With the progress of surgical techniques and increased awareness of the importance of the psychological impact on patients, more attention is being given to the quality of life (QoL). In 2002, Taylor et al. developed the Neck Dissection Impairment Index (NDII) questionnaire [4], a 10-item instrument that assesses several aspects of everyday life following ND. To date, this is the only tool assessing QoL in head and neck cancer patients that specifically analyses the physical and psychological impact of ND. The aim of our study was to develop and validate an easily usable version of the NDII questionnaire for Italian-speaking patients.

Materials and methods

Patients

The study group was selected among all patients consecutively treated with ND for any head and neck cancer between 1st January 2019 and 31st December 2019 at the Department of Otolaryngology - Head and Neck Surgery of Cattinara Hospital (Trieste, Italy). Eligibility criteria included previously untreated and diagnosed head and neck cancer and concurrently requiring ND as part of the management of the cancer, no neurological associated disease, and cognitive ability within normal limits (Mini-Mental State Examination > 25, corrected for age and educational level) [5]. Patients were excluded if they had undergone surgery less than 11 months previously, reported any history of unrelated neck or shoulder pathological conditions, had known recurrent disease at the time of evaluation, or had a lack of basic written and oral command of the Italian language.

Demographic data were collected retrospectively, together with clinical and pathological tumour stage using the 8th edition of American Joint Committee on Cancer. (AJCC)/ Union Internationale Contre le Cancer (UICC)/TNM classification [6]. Neck dissections were defined according to the classification provided by the American Academy of Otolaryngology – Head and Neck Surgery in 1991 and subsequent updates [7].

To evaluate the test-retest reliability of the NDII, the questionnaire was administered twice approximately 2 weeks apart to all patients enrolled. This interval period was selected because no substantial change was expected to take place in the subjects' condition within this period. When completing the second NDII, the subjects did not have the chance to check their responses on the previous questionnaires.

Translation and cross-cultural adaptation

Cross-cultural adaptation of the NDII questionnaire was performed using standard techniques [8]. Items of the original NDII were translated into Italian by a professional translator and two bilingual investigators. Two independent otolaryngologists familiar with the process of instrument validation examined semantic, idiomatic and conceptual issues to further refine these versions. A final consensus version was obtained and given to two professional translators to produce a literal translation into English. The two translators and an expert committee synthesised the results of the translations in an English back-translated version that was compared with the original to check that they had the same semantic value. Points of disagreement were resolved, as shown in the section "translation" of the results chapter. The final Italian version is shown in Table I.

Questionnaire and calculation of the final score

The NDII is a 10-item validated questionnaire. The translated and adapted final copy of the questionnaire was administered to the patients twice approximately 2 weeks apart. The patients were asked how much they had been bothered by the listed symptoms in the past 4 weeks, on a 5-point scale: "not at all," "a little bit," "a moderate amount," "quite a bit," or "a lot". Scoring was achieved by rating the item responses from 1 to 5, with 5 representing better quality of life related to neck dissection. The single scores were summed up to obtain a raw score, which was then transformed to a 0 to 100-point scale by applying the following equation: [(raw score - 10)/40] x 100.

Statistics

Continuous variables were expressed as means and standard deviation or medians and interquartile ranges, according to data distribution determined with the Shapiro-Wilk test. Categorical variables were summarised as counts and percentages. Means were compared using the Student t-test. The X^2 test was used to compare percentages. Internal consistency was tested using Cronbach's coefficient alpha. Values ≥ 0.7 were regarded as satisfactory [9]. Reproducibility, or test-retest reliability, was assessed using Pearson's correlation coefficient between the first and the second administrations of the questionnaire.

Table Ia. English translation of the Italian version of the Neck Dissection Impairment Index Questionnaire.

With regard to the treatment received on your neck for your cancer, how much discomfort have the following caused you over the past 4 weeks?				
Q1. Have you suffered from pain or discomfort in your neck or shoulder?				
☐ Not at all	☐ A little bit	☐ A moderate amount	☐ Quite a bit	☐ A lot
Q2. Have you experienced stiffness in your neck or shoulder?				
☐ Not at all	☐ A little bit	☐ A moderate amount	☐ Quite a bit	☐ A lot
Q3. Have you experienced limitations in looking after yourself because of your neck and shoulder (e.g., combing your hair, dressing, washing yourself, etc.)?				
☐ Not at all	☐ A little bit	☐ A moderate amount	☐ Quite a bit	☐ A lot
Q4. Have you been limited in lifting light objects because of your neck or shoulder?				
☐ Not at all	☐ A little bit	☐ A moderate amount	☐ Quite a bit	☐ A lot
Q5. Have you been limited in lifting heavy objects because of your neck or shoulder?				
☐ Not at all	☐ A little bit	☐ A moderate amount	☐ Quite a bit	☐ A lot
Q6. Have you been limited in reaching up for objects placed high up (e.g., on shelves, tables counters) because of your neck or shoulder?				
☐ Not at all	☐ A little bit	☐ A moderate amount	☐ Quite a bit	☐ A lot
Q7. Have you suffered limitations in your overall activities because of your neck or shoulder?				
☐ Not at all	☐ A little bit	☐ A moderate amount	☐ Quite a bit	☐ A lot
Q8. Has the treatment you received affected your participation in social activities?				
☐ Not at all	☐ A little bit	☐ A moderate amount	☐ Quite a bit	☐ A lot
Q9. Has your neck or shoulder limited your ability to carry out leisure or recreational activities?				
☐ Not at all	☐ A little bit	☐ A moderate amount	☐ Quite a bit	☐ A lot
Q10. Has your neck or shoulder limited your ability to work (including work at home)?				
☐ Not at all	☐ A little bit	☐ A moderate amount	☐ Quite a bit	☐ A lot

Table Ib. Italian version of the Neck Dissection Impairment Index Questionnaire.

Riguardo il trattamento ricevuto al collo per la sua neoplasia, quanto disagio le hanno causato i seguenti disturbi nelle ultime 4 settimane?				
Q1. Ha avuto disagi causati dal dolore o dal fastidio al collo o alla spalla?				
☐ Per nulla	☐ Poco	☐ Moderatamente	☐ Abbastanza	☐ Molto
Q2. Ha avuto disagi causati dalla rigidità del collo o della spalla?				
☐ Per nulla	☐ Poco	☐ Moderatamente	☐ Abbastanza	☐ Molto
Q3. Ha avuto disagi legati a limitazioni nel prendersi cura di se stesso a causa del collo o della spalla (ad esempio, pettinarsi, vestirsi, lavarsi, etc.)?				
☐ Per nulla	☐ Poco	☐ Moderatamente	☐ Abbastanza	☐ Molto
Q4. Si è sentito/a limitato/a, a causa del collo o della spalla, nel sollevare oggetti leggeri?				
☐ Per nulla	☐ Poco	☐ Moderatamente	☐ Abbastanza	☐ Molto
Q5. Si è sentito/a limitato/a, a causa del collo o della spalla, nel sollevare oggetti pesanti?				
☐ Per nulla	☐ Poco	☐ Moderatamente	☐ Abbastanza	☐ Molto
Q6. Si è sentito/a limitato/a, a causa del collo o della spalla, nel prendere oggetti posti in alto (ad esempio, su mensole, su tavoli o banconi)?				
☐ Per nulla	☐ Poco	☐ Moderatamente	☐ Abbastanza	☐ Molto
Q7. Ha avuto disagi legati alle sue attività in genere a causa del collo o della spalla?				
☐ Per nulla	☐ Poco	☐ Moderatamente	☐ Abbastanza	☐ Molto
Q8. La terapia che ha ricevuto al collo ha condizionato la sua partecipazione ad attività sociali?				
☐ Per nulla	☐ Poco	☐ Moderatamente	☐ Abbastanza	☐ Molto
Q9. Il collo o la spalla hanno limitato le sue capacità nell'eseguire attività di piacere o ricreative?				
☐ Per nulla	☐ Poco	☐ Moderatamente	☐ Abbastanza	☐ Molto
Q10. Il collo o la spalla hanno limitato la sua capacità di lavorare (inclusi i lavori a casa)?				
☐ Per nulla	☐ Poco	☐ Moderatamente	☐ Abbastanza	☐ Molto

P values < 0.05 (two-sided) were considered statistically significant. Statistical analyses were performed using SPSS Version 26 (IBM Corp., Armonk, NY, USA).

Results

Patient and disease characteristics

Sixty-three patients underwent neck dissection at our centre during the selected period. Six had received previous neck surgery, four had received previous radiotherapy, five were lost to follow-up, one refused to participate in the study for personal reasons, four did not complete the second copy of the questionnaire and one showed cognitive decline according to the Mini-Mental State Examination. Finally, a total of 42 patients completed both copies of the translated questionnaires, 19 (45.2%) females and 23 (54.8%) males, with a mean age 67.5 years (2.0).

The primary tumours mainly involved the oral cavity (24/42, 57.1%). The most common histology was squamous cell cancer (37/42, 88.1%). Most patients presented with a cN0-cN1 neck (17/42 [40.5%], 14/42 [33.3%], respectively). Patient and disease characteristics are summarised in Table II.

Treatment characteristics

Eleven patients received bilateral ND; of these, two patients also completed the original English version of the questionnaire. Twelve patients received adjuvant radiotherapy (12/42, 28.6) and seven adjuvant chemotherapy (16.7%). Details on the type of neck dissection and adjuvant treatment are listed in Table III.

Translation

In the review of the forward translations into Italian the translators had 3 points of disagreement. Of these, all represented different wordings, but the meaning was the same. More in detail, the inconsistencies regarded the following expressions:

- "treatment" (Pre-question box, question 8); the words "trattamento" and "terapia" have been proposed; a consensus was obtained on "terapia" since it is more specific for a medical context, while "trattamento" includes non-medical practices;
- "...bothered..." (Pre-question box, questions 1-2-3-7); the words "disturbo" and "disagio" have been proposed; a consensus was obtained on "disagio" since this word better includes the psychological aspects related to the disease;
- '...work at home...' according to original paper, the wording referred to both working from home and housework (question 10); among various translations ("lavori a casa", "lavori domestici", "faccende domestiche") we opted for "lavori a casa", that appeared more inclusive and reflected the original meaning.

Table II. Patient and disease characteristics. Continuous variables are reported as mean (standard deviation). Categorical variables are reported as number (percentage).

Patient and disease characteristics	n = 42
Age	67.5 (2.0)
Gender	
Male	23 (54.8)
Female	19 (45.2)
BMI	26.0 (3.8)
Primary tumour	
Oral cavity	24 (57)
Oropharynx	7 (16.7)
Larynx	3 (7.1)
Hypopharynx	1 (2.4)
Thyroid	2 (4.8)
Salivary glands	2 (4.8)
Facial skin	1 (2.4)
Unknown primary	2 (4.8)
Histology	
Squamous cell carcinoma	37 (88)
Adenoid cystic carcinoma	1 (2.4)
Melanoma (skin)	1 (2.4)
Papillary thyroid carcinoma	2 (4.8)
Malignant peripheral nerve sheath tumour	1 (2.4)
cT	
X	2 (4.8)
1	7 (16.7)
2	14 (33.3)
3	6 (14.3)
4	13 (31.0)
cN	
0	17 (40.5)
1	14 (33.3)
2b	6 (14.3)
2c	2 (4.8)
3b	3 (7.1)
Tumour stage	
I	11 (26.2)
II	12 (28.6)
III	10 (23.8)
IVa	4 (9.5)
IVb	5 (11.9)

Table III. Characteristics of neck dissection and adjuvant therapy. Data are reported as number (percentage).

Treatment characteristic	All n = 42
Neck dissection*	53 (100.0)
Unilateral	31 (73.8)
Bilateral	11 (26.2)
Side*	
Right	30 (56.6)
Left	23 (43.4)
Type*	
Selective 1-3	15 (28.3)
Selective 1-4	12 (22.6)
Selective 2-4	5 (9.4)
Radical	3 (5.7)
Modified radical	18 (34.0)
Preserved IJV**	17 (94.4)
Preserved SCM**	18 (100.0)
Preserved SAN**	15 (83.3)
Adjuvant radiotherapy	
Yes	12 (28.6)
No	30 (71.4)
Adjuvant chemotherapy	
Yes	7 (16.7)
No	35 (83.3)

** Percentage refers to the total of the neck dissections per group. ** Percentage refers to the total of modified radical ND per group. IJV: internal jugular vein; SCM: sternocleidomastoid.*

Table IV. Validation tests of the Italian version of the Neck Dissection.

	r	p-value
Internal consistency test		
Cronbach alpha = 0.95		
Test-retest correlation		
Q1	0.87	< 0.001
Q2	0.82	< 0.001
Q3	0.88	< 0.001
Q4	0.80	< 0.001
Q5	0.77	< 0.001
Q6	0.90	< 0.001
Q7	0.82	< 0.001
Q8	0.76	< 0.001
Q9	0.76	< 0.001
Q10	0.84	< 0.001
Total	0.95	< 0.001
Italian-English test-retest correlation		
Q1	0.94	< 0.001
Q2	0.90	< 0.001
Q3	0.94	< 0.001
Q4	0.73	0.02
Q5	0.76	0.01
Q6	0.99	< 0.001
Q7	0.94	< 0.001
Q8	0.73	0.02
Q9	0.95	< 0.001
Q10	0.94	< 0.001
Total	0.98	< 0.001

Reliability

Internal consistency proved to be excellent, with Cronbach's alpha = 0.95.

Test-retest reliability for the Italian version was confirmed by the Pearson correlation coefficient ($r = 0.95$, $N = 53$, $p < 0.001$). A significant test-retest reliability was also found between the Italian and the English version ($r = 0.98$, $N = 12$, $p < 0.001$). All items showed a Pearson's $r > 0.70$, in the test-retest reliability analysis. Detailed results of the reliability tests are reported in Table IV.

Discussion

QoL following cancer treatment is important because of the long-term effects on activities of daily living and employment [10]. The growing rates of HPV-induced oropharyngeal cancers have, in fact, lowered the mean age at onset of these tumours throughout the world [11]. While various tests for the assessment of QoL have been published in the literature, only one provides a focused analysis of the effects of ND on QoL. The NDII questionnaire was developed by Chepeha et al. in 2002 and since then it has been used in several studies in English-speaking populations [4,12,13]. The questionnaire has also been used as a comparison for the validation of less specific instruments, such as the Disabilities of the Arm, Shoulder, and Hand (DASH) questionnaire for use in patients after ND for head and neck cancer [14]. As for other languages, the NDII has been used in a study on Dutch patients even though, to our knowledge, no official validation in Dutch exists [15]. Recently, the questionnaire has been translated into Danish and validated on a sample of 10 patients [11]. Ours is therefore the second study that would lead to validation of the NDII questionnaire in another language, and on a larger patient population. Other questionnaires investigating QoL outcomes following head and neck cancer treatments have also been validated [16-18]. Marchese et al. demonstrated the reliability of the "University of California - Los Angeles (UCLA) Shoulder Scale", of the "Shoulder Pain and Disability Index" (SPADI) and the Simple Shoulder Test (SST) [18]. However, although valu-

able and widely adopted, these questionnaires focus on motor functionality following ND without taking into account the psychological aspects covered by the NDII questionnaire. The problems of translation from Italian (or any Romance language) to English can be cultural and not purely linguistic. Besides linguistic issues (e.g. resolving the indeterminate gender/number) literal translation of some English expressions can lead to conceptual misunderstanding. In this work, we have an example of this translating the word "treatment" whose literal translation is "trattamento". Both the words "trattamento" and "terapia" could be used to indicate a surgical or a medical therapy but, the word "trattamento" includes non-medical practices while "terapia" is more specific for a medical context. For this reason, we chose in agreement the word "terapia". In the case of the word "...bothered..." the words "disturbo" and "disagio" were proposed; a consensus was obtained on "disagio" since this word better includes the psychological aspects related to the disease. Finally, as already stated, '...work at home...' could be used to indicate both working from home and housework (question 10); among various translations we opted for "lavori a casa", which appeared more inclusive due to the fact that, in Italian, the plural use of the word reflects more housework while the singular use of the word "lavoro" indicates the main job of a person that can be done at home (e.g. use of the PC on smartworking).

Conclusions

Our data suggest that the Italian version of the NDII questionnaire represents a reliable and useful tool for head and neck surgeons, and we hope that further studies will be possible thanks to its translation and validation.

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Conflict of interest statement

The authors declare no conflict of interest.

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Authors' contributions

AVM, ES and GT: ideation, draft and review. VC and PB-R: draft and review. NG: review. DC: ideation and review.

Ethical consideration

This study was performed in accordance with the ethical standards of the National Research Committee and with the 1964 Helsinki Declaration and its later amendments**.** Informed consent to the use of their data was obtained from all the participating individuals. Patient data was collected retrospectively. Approval from the ethics committee is not required for this type of study in our institution.

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