HEAD AND NECK

Motor and functional recovery after neck dissection: comparison of two early physical rehabilitation programmes

Recupero motorio e funzionale dopo dissezione latero-cervicale del collo: due programmi di fisioterapia precoce a confronto

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SUMMARY

The aim of this prospective, single-centre, non-randomized explorative study is to comparatively assess two-month results of two early rehabilitation programmes in patients receiving neck dissection for head and neck cancer, with the hypothesis that those not receiving therapist-assisted physiotherapy would take an active role in their own rehabilitation to enhance outcomes. At the European Institute of Oncology, Milan (Italy), 97 patients were registered during the pre-hospitalization period and divided into an Autonomous group (living distant from the hospital) and a Physio group (living near). As expected, only 50 patients (25 per group) completed the study. Both groups received a Physical Therapy Brochure with instructions on to how to perform exercises at home. Home physical exercises started five days after surgery and continued for two months. The Autonomous group received a pre-surgery instruction session; the Physio group attended four once-weekly therapist-guided physiotherapy sessions. Two months after surgery, arm mobility and pain had recovered to pre-operative levels. Most endpoints, including the main composite, did not differ between groups. Although longer-follow-up is necessary, early physiotherapy seems to be effective in maintaining arm mobility and reducing pain, even in patients empowered to do exercises autonomously.

KEY WORDS: Neck dissection • Physiotherapy • Rehabilitation

RIASSUNTO

Lo scopo di questo studio esplorativo, prospettico, monocentrico e non randomizzato è di valutare e comparare i risultati a due mesi di due programmi di riabilitazione precoce, in pazienti sottoposti a dissezione latero cervicale del collo, con l'ipotesi che coloro che non ricevono fisioterapia assistita dal fisioterapista siano incentivati ad intraprendere un ruolo attivo nella propria riabilitazione, con la possibilità di raggiungere un miglioramento degli outcome. Presso l'Istituto Europeo di Oncologia, Milano (Italia), sono stati arruolati 97 pazienti in pre-intervento e sono stati divisi in un gruppo Autonomo (residenti lontano dall'ospedale) e in un gruppo Fisioterapia (Fisio) (residenti vicino all'ospedale). 50 pazienti (25 per gruppo) hanno completato lo studio. Entrambi i gruppi hanno ricevuto una Brochure di fisioterapia contenente informazioni riguardanti lo svolgimento degli esercizi a domicilio. Il programma di esercizi è iniziato cinque giorni dopo la chirurgia ed è durato due mesi. Il gruppo Autonomo ha eseguito una seduta educativa pre-intervento; il gruppo Fisio ha eseguito quattro sedute di fisioterapia con l'assistenza del fisioterapista, una volta a settimana per quattro settimane. Due mesi dopo la chirurgia, la mobilità dell'arto e il dolore sono stati confrontati con gli stessi parametri pre-intervento. La maggior parte degli endpoint sono risultati sovrapponibili tra i due gruppi. Sebbene sia necessario un follow-up più a lungo termine, la fisioterapia precoce sembra efficace nel mantenere la mobilità dell'arto e nel ridurre il dolore, anche in pazienti che, adeguatamente formati, eseguono gli esercizi autonomamente.

PAROLE CHIAVE: *Dissezione del collo • Fisioterapia • Riabilitazione*

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Introduction

Surgery combined with radiotherapy, chemotherapy or both is the gold standard treatment for head and neck cancers. Surgery aims to remove all disease. However, this often results in functional and aesthetic impairment, so immediate reconstruction using local, regional or free flaps, is usually associated with radical surgery.

Head and neck surgery often includes dissection of the lateral cervical lymph nodes, usually on the disease side, but sometimes bilaterally. The lymph nodes may harbour metastases that are a source of further metastatic spread [1]. Several neck dissection protocols, varying in number of

lymph node stations (and associated anatomic structures) removed, are routinely employed. Radical neck dissection is complete removal of nodes from levels I-V together with removal of the sternocleidomastoid muscle, jugular vein and spinal accessory nerve. Various modifications of radical neck dissection have been developed to provide better functional results with conserved oncological radicality. Modified neck dissection is complete removal of level I-V nodes with sparing of some neck structures. In type I modified neck dissection, only one among the spinal accessory nerve, jugular vein and sternocleidomastoid muscle is preserved; type II dissection involves preservation of two of these structures, and in type III all three are preserved.

Selective neck dissection is complete removal of nodes at greatest risk for metastasis, while levels at lower risk are spared. There are four procedures: supraomohyoid dissection, which includes removal of levels I, and II and III; posterolateral dissection with removal of level II-V node stations; anterior dissection, which removes level VI nodes; and lateral dissection, which removes level II-IV nodes [2-5].

Injury to the spinal accessory nerve, which provides motor innervation to the sternocleidomastoid and trapezius, results in pain, loss of mobility and strength and deformity of the shoulder homolateral to the dissection [6-11]. This collection of symptoms is referred to as neck dissection syndrome [12], 11th nerve syndrome [13] or spinal accessory nerve syndrome [14].

Several studies indicate that physical therapy is useful against neck dissection syndrome [7 10 12 15-28]. Most studies have employed physiotherapy, but did not describe the protocol in sufficient detail for it to be reproducible. Interventions reported include massage [16]; hot packs, gravity-assisted pendular exercises [12]; active, assisted and passive exercises [10 12 16 20 24 25 27 29 30]; proprioceptive neuromuscular facilitation [18 20 27]; active neck mobilization [25]; interferential therapy and faradic stimulation [16]; stretching [20 24 29 30]; infrared radiation [24]; isokinetic muscle strengthening [12-18]; and progressive resistance exercise training [28-30].

However, notwithstanding this wide variety of interventions, very few comparative studies have been performed, as noted by Lauchlan [23]. In fact, to our knowledge only two studies have compared the efficacy of different therapeutic protocols [10 30]. Furthermore, most studies did not employ an early protocol whose intention was to prevent the emergence of neck dissection syndrome and other side effects, but started two months or more after surgery; although one study started therapy 15-30 days after surgery [10]. Several studies [10 22 30] have stressed the importance of reducing the post-surgical immobility period, in order to reduce the chances of developing chronic shoulder joint malfunction.

The World Health Organization [31] has urged that rehabilitation interventions for patients with chronic diseases should be cost-effective, evidence-based and encourage patient empowerment. Several studies have reported on interventions designed to encourage the patient to be more proactive with regards to his/her medical and health care [27 32-39]. In line with the WHO recommendations, we feel that one of the aims of physical therapy programmes after neck dissection should be to encourage patients to take control of their own rehabilitation.

The aim of the present study was compare two early physical therapy rehabilitation programmes in patients who had undergone surgery with neck dissection for head and neck cancer. In both programmes, patients performed rehabilitation exercises at home as soon as possible after surgery. In one programme, patients also attended therapist-assisted physiotherapy sessions in addition to home exercises; in the other programme, patients received only a pre-surgery instruction session one of whose aims was to encourage patients to take a proactive role in their own rehabilitation.

The main aim was to investigate the efficacy of both early intervention programmes, but we were also interested in whether those not receiving therapist-assisted physiotherapy sessions would take an active role in their own rehabilitation to enhance outcomes.

Materials and methods

Study design

This was a prospective, single-centre, non-randomized explorative study with two arms: the Autonomous group, which did physiotherapy at home guided by a single preoperative instruction session and a take-home instruction brochure; and the Physio group that also did physiotherapy at home, but in addition attended a therapist-conducted physiotherapy programme. The study was approved by the ethical review board of the European Institute of Oncology. Eligible participants gave written informed consent.

Participants

Patients were enrolled during the pre-hospitalization period. Eligible patients were those with head and neck cancer scheduled for unilateral or bilateral neck dissection, ECOG performance status 0-2, age ≤ 65 years, life expectancy > 3 months, ability to rotate the head by ≥ 60°, and ability to perform complete passive abduction of the involved arm (by 180°), with strength of complete arm abduction in the frontal plane ≥ 3 on the MRC scale [40]. Patients undergoing immediate reconstruction with a pectoralis major flap were excluded as it is associated with poorer functional recovery than other kinds of reconstruction (or no reconstruction) after head and neck surgery [25 41 42]; early physical therapy may compromise outcomes in these patients.

Other exclusion criteria were cervical or shoulder injury, concomitant illness including but not limited to on-going

psychiatric illness, and any situation that might compromise compliance with study requirements. Patients were asked to declare their willingness and ability to participate in the study for its entire duration and were required to not undergo other types of physiotherapy during the study period.

For logistic reasons, patients were allocated to the study arms non-randomly: those living outside the Region of Lombardy (northern Italy) were assigned to the Autonomous group; those living within the Region of Lombardy were assigned to the Physio group.

Rehabilitation programmes

Patients in the Autonomous group received an Instruction Session. Both groups received the Physical Therapy Brochure that contained instructions on to how to perform the exercise. Both groups had to perform the exercises at home. Physio group patients additionally attended the therapist-aided Physical Therapy Programme.

The Instruction Session consisted in a meeting between the physiotherapist and patient in the patient's hospital room on the day before surgery (after study enrolment), that lasted about 30 min. The physiotherapist explained the basic anatomy and physiology of the dissected neck area, and that lymph node removal could cause nerve damage – with pain, discomfort, weakness and compromised neck mobility as possible outcomes. To counteract these possibilities, it was stressed that home exercises should be started as soon as possible after the operation and performed twice a day every day at least until evaluation two months post-surgery. The exercises to be performed were described (they were the same as those described in the Physical Therapy Brochure). Exercises and strategies to reduce bad postural habits, pain and feelings of heaviness were also described.

The Physical Therapy Brochure described the nine exercises to be performed (Fig. 1):

(a) relaxation through deep breathing in a supine position for three minutes;
(b) flexing the arm completely in a supine position, while supporting the body with the opposite arm;
(c) complete abduction of the arm, not against gravity, in the supine position;
(d) rotating the head to the left and right in the sitting position;
(e) tilting the head to the left and the right, in the sitting position;
(f) flexing and extending the head back and forth, in the sitting position;
(g) raising and lowering the shoulders, in the sitting position;
(h) moving the shoulders backwards and forward, in a sitting position; and
(i) holding a stick in front of the body parallel to the ground with both hands, then raising it above the head and taking it to the nape of the neck while flexing the elbows.

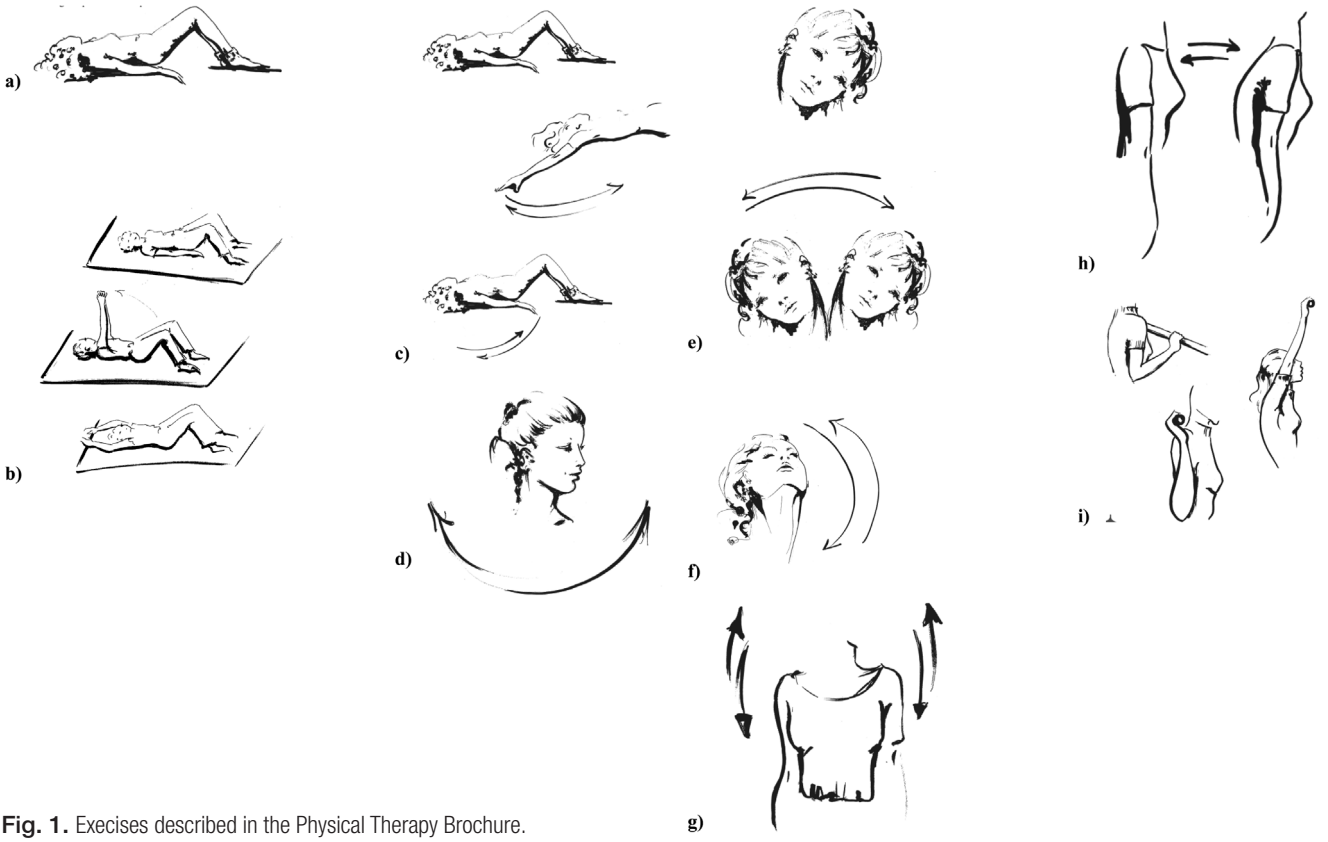

Fig. 1. Execises described in the Physical Therapy Brochure.

The Brochure stated that each exercise had to be repeated 5 times and that exercise sessions had to be performed twice a day for at least two months.
The Physical Therapy Programme consisted of four once-weekly physiotherapy sessions of 50 min each, starting 5 days after surgery. All sessions started with pectoral muscle stretching. These muscles are often contracted as patients tend to assume a protective pain-minimizing posture in the postoperative period. Scar massaging initiated as soon as possible after the operation on order to soften tissues and make them more elastic. The other exercises included passive mobilization, assisted-active mobilization and active mobilization of the neck and arm, designed to regain the complete range of motion reduced by scar tension and pain. Active mobilization was performed against resistance to avoid the development of muscle weakness. Particular attention was paid to working the upper trapezius, which can atrophy following spinal accessory nerve damage. To work the arm and shoulders, diagonal-spiral progressive active and action assisted shoulder exercises were performed in conjunction with proprioceptive neuromuscular facilitation exercises without resistance (D1 into flexion from hitch hike to swat fly, and into extension from swat fly to hitch hike, and D2 into flexion from hand in opposite pocket to carry tray, and into extension from carry tray to hand in opposite pocket; in all cases with the elbow straight) [43]. Patients did not necessarily do all exercises at the beginning; however, the number of exercises performed increased as patients improved.

Endpoints and their assessment
The primary endpoint of the study was motor/mobility recovery at two months. Secondary outcomes were quality of life, arm functional status, pain and postoperative drug consumption to control pain, all assessed at two months. Data on adherence to 'outside' physiotherapy programmes (exclusion criterion), compliance with exercises and the clarity of the exercises described in the Physical Therapy Brochure were also collected. A subsequent study will assess outcomes a year after surgery.
Motor/mobility recovery at two months had three components: recovery of arm mobility (passive abduction) relative to pre-surgical evaluation; recovery of arm strength relative to pre-surgical evaluation; and recovery of neck mobility (head rotation) relative to pre-surgical evaluation.
If patients had ≥ 90% recovery of arm mobility, ≥ 90% recovery of neck mobility and complete recovery of arm strength they were considered to have made a "good" recovery and this was the composite primary endpoint.
Neck mobility was always evaluated bilaterally even for unilateral neck dissections since the scar can affect mobility on the contralateral side; for a "good" score neck mobility recovery had to be at least 90% on both sides. For patients undergoing bilateral surgery, recovery had to be good on both sides to obtain the overall "good" score.
Patients who did not have "good" recovery at two months were encouraged to continue the programme at home once a day for four additional months, since electromyographic studies indicate that compromise of nerve conduction after neck dissection can last three to six months [15 44].

Neck mobility assessment
The extent of head rotation at the neck was measured in degrees with a universal full-circle manual protractor, with the patient sitting, the head facing forwards and the shoulders immobile. The fulcrum of the protractor was placed at the centre of the top of the head, one arm of the protractor was lined up to the line to the acromion; the other arm was lined up with the tip of the nose, measuring the angle covered by the arms in the horizontal plane around the vertical axis. During head rotation the shoulders were held immobile, to avoid rotation of the vertebral column at levels lower than the cervical vertebrae [40 45 46].

Arm mobility assessment
A universal full-circle manual protractor was used to measure the range of complete passive shoulder abduction, in the frontal plane with the patient prone. The protractor fulcrum was placed on the rear face of the shoulder joint, below the acromion. One arm of the protractor was aligned with the line parallel to the spinal apophysis. The other arm was aligned with the median line of the humeral diaphysis, along the rear face of the humerus, to evaluate arm movement in the frontal plane around the anterior-posterior axis. During arm movements the thorax was held immobile avoiding lateral flexion of the vertebral column [40 45 46].

Arm strength assessment
Arm strength was evaluated with the MRC scale during complete arm abduction [47]. With the patient supine, the arm moved over a smooth board in the horizontal plane, around the vertical axis from 0 to 180°. Scores were 0 = no movement; 1 = minimal movement; 2 = complete movement.
With the patient sitting in a chair, the arm was abducted in the coronal plane, from the 0° position to 180°. Scores were 3 = complete movement against gravity; 4 = complete movement against a medium resistance exerted by the examiner; 5 = complete movement with normal strength against maximal resistance (strongest resistance allowing completion of the movement once).

Level of functioning, quality of life, head and neck symptoms, pain
Level of functioning and quality of life was assessed by a validated Italian version of the EORTC QLQ-C30 for cancer patients [46-50]. The QLQ-C30 has 30 questions

exploring five functional domains (physical functioning, role functioning, emotional functioning, cognitive functioning and social functioning). Quality of life is assessed by questions 29 (How would you rate your overall health during the past week?) and 30 (How would you rate your overall quality of life during the past week?) of the QLQ-C30. Arm functioning was assessed by questions 1, 5, 6 and 7 of the QLQ-C30, combined to give an overall score (maximum 100). The questions were: Do you have any trouble doing strenuous activities, like carrying a heavy shopping bag or suitcase? Do you need help with eating, dressing, washing yourself or using the toilet? During the past week were you limited in doing either your work or other daily activities? During the past week were you limited in pursuing your hobbies or other leisure time activities?

Head and neck symptoms were assessed by a validated Italian version of the EORTC QLQ-H&N35 for head and neck patients [51 52]. QLQ-H&N35 has 33 questions exploring seven symptoms domains (pain, swallowing, senses problems, speech problems, trouble with social eating, trouble with social contact and less sexuality).

Pain was also assessed on a 10-point visual analogue scale (VAS), range 0 (no pain) to 10 (worst pain imaginable) in the entire shoulder and neck region. NSAIDS consumption was assessed at two months after surgery by asking patients.

Statistical analysis

For categorical variables, summary tables were erected and percentages compared with Pearson's chi-square test. For continuous variables, medians with interquartile range (IQR) were calculated and compared with Wilcoxon's sum rank test.

The two physiotherapy programmes were compared on the composite endpoint overall functional status at 2 months, and the individual endpoints, using univariable and multivariable logistic regression. The models provided crude and adjusted of odds ratios (ORs) with 95% confidence intervals (CI) of attaining endpoints; however, differences between the two groups were assessed using the Wald chi-square test. Adjustments were for side of dissection, bilateral *vs.* unilateral dissection, sex and age. All tests were two-sided, with p values ≤ 0.05 considered significant. The analyses were performed with SAS statistical software, version 8.02 for Windows. We also analyzed outcomes in the unilateral dissection *vs.* bilateral dissection groups.

Results

From August 2006 to December 2008, 97 patients were registered for the study. In line with expectations, just over half completed the study (50 patients, 25 per group). Reasons for withdrawal are shown in Table I. Patient and neck dissection characteristics are shown in Table II, and the results of the pre-surgical motor evaluation are shown in Table III. From Tables II and III it is evident that the two groups of completers were well-balanced for type of surgery, extent of neck dissection and most other characteristics except sex. After surgery, 20 patients (8 the Autonomous group; 12 in the Physio group, p = 0.25) required NSAIDS to control their pain (Table IV); these were taken for a mean of 3.5 days by Autonomous group patients and 7 days by Physio group patients (p = 0.1).

Both pre-operatively and two months after the operation, median pain level was 0 on the VAS scale in both groups (Table V). Changes in pain score from the preoperative to two-month assessment did not differ between the two groups (p = 0.26).

Most patients said they performed the autonomous exercises 14 times per week, with no significant difference between groups (p = 0.28,

Table I. Reasons for withdrawal from the study.

	Autonomous group	Physio group	Total
Enrolled	52	45	97
Withdrawal at 2-month postoperative follow-up for:			
Protocol violation	10	6	16
Follow-up visit at < 2 months	1	0	
Neck dissection not performed	0	2	
Reconstruction with pectoralis flap	3	1	
Other concomitant physiotherapy	3	1	
Informed consent withdrawn	1	1	
Surgery not performed	2	1	
Post-operative complication	**4**	**9**	**13**
Development of fistula	2	5	
Urgent hospitalization for liver disease	0	1	
Severe postoperative hemorrhage	0	1	
Subcutaneous submandibular emphysema	0	1	
Abscess	0	1	
Persistent induration of neck muscles suggesting extensive fibrosis and inability to regain muscle strength and movement	1	0	
Nerve resection	1	0	
Lost to follow-up	7	4	11
Death before follow-up	2	1	3
Two-month follow-up not performed due to on-going chemotherapy or radiotherapy	4	0	4
Total withdrawals	27	20	47
Evaluable for efficacy analysis	25	25	50

Table II. Characteristics of patients who completed the study.

Characteristic		Autonomous group (n = 25)	Physio group (n = 25)	p value^
Age (continuous)	Median (range)	49 (16-64)	56 (30-65)	0.43
Age (2 classes)	≤ 50 years (%)	13 (52)	9 (36)	0.25
	> 50 years (%)	12 (48)	16 (64)	
Sex	M (%)	21 (84)	14 (56)	0.03
	F (%)	4 (16)	11 (44)	
Education	Primary school (%)	1 (4)	6 (24)	0.169
	Secondary school (%)	7 (28)	7 (28)	
	High school (%)	12 (48)	10 (40)	
	College degree (%)	5 (20)	2 (8)	
Side of neck	Right (%)	10 (40)	12 (48)	0.09
	Left (%)	5 (20)	9 (36)	
	Bilateral (%)	10 (40)	4 (16)	
Type of neck dissection	Radical (%)	0 (-)	0 (-)	
	Modified type I (%)	1 (4)	0 (-)	
	Modified type II (%)	1 (4)	2 (8)	
	Modified type III (%)	14 (56)	10 (40)	
	Selective (sup. to hyoid; no level V) (%)	0 (-)	1 (4)	
	Selective (posterolateral) (%)	8 (32)	10	
	Selective (no level V) (%)	1 (4)	2 (8)	
Type of surgery	Neck dissection (ND)	8 (32)	11 (44)	
	Trans-oral removal of oral cavity tumour + ND (%)	2 (8)	0 (-)	
	Laryngectomy + ND (%)	3 (12)	2 (8)	
	Mandibulectomy + ND (%)	2 (8)	2 (8)	
	Mandibulotomy + ND (%)	8 (32)	2 (8)	
	Maxillectomy + ND (%)	1 (4)	1 (4)	
	Parotidectomy + ND (%)	1 (4)	1 (4)	
	Thyroidectomy + ND (%)	0 (-)	4 (16)	
	Pull-through glossectomy + ND (%)	0 (-)	2 (8)	
Type of pre-treatment	No pre-treatment (%)	16 (64)	13 (52)	
	Surgery to primary (%)	6 (24)	9 (36)	
	Surgery to primary and neck (%)	1 (4)	2 (8)	
	Chemotherapy + surgery to primary (%)	1 (4)	0 (-)	
	Chemotherapy + radiotherapy (%)	1 (4)	0 (-)	
	Radiotherapy (%)	0 (-)	1 (4)	
T stage	T0 (%)	1 (4)	1 (4)	
	T1 (%)	1 (4)	1 (4)	
	T2 (%)	4 (16)	2 (8)	
	T3 (%)	1 (4)	4 (14)	
	T4a (%)	9 (36)	5 (20)	
	Tx (%)	8 (32)	11 (44)	
	Not available (%)	1 (4)*	1 (4)**	
Nodal status of neck	N0 (%)	6 (24)	8 (32)	
	N1 (a,b) (%)	6 (24)	9 (36)	
	N2 (a,b,c) (%)	10 (40)	7 (28)	
	N3 (%)	2 (8)	0 (-)	
	Not available (%)	1 (4)*	1 (4)**	

** Leiomyosarcoma; ** Melanoma; ^ Medians compared by non-parametric Wilcoxon test; frequencies compared by Chi-square test; chi-square test only performed for variables when number of cells with absolute frequency > 2 was greater than 60% of total number of cells.*

Table IV). All patients reported that the exercises were clearly described in the Brochure. Primary outcomes two months after surgery are shown in Table VI. Twenty-three patients (92%) in each group recovered ≥ 90% of arm mobility (passive abduction). Eight (33%) patients in the Autonomous group and 7 (28%) patients in the Physio group totally recovered arm strength. Eleven (44%) patients in the Autonomous group and 15 (60%) patients in the Physio group recovered ≥ 90% of head rotation. Five (20%) patients in each group had good motor recovery (composite endpoint). For none of the primary endpoints did the two groups differ significantly. Table VI shows arm strength recovery in the two groups two months after surgery.

All patients who completed the study also completed the QLQ-C30 and QLQ-H&N35 questionnaires (Table VII). The two groups were fairly similar in terms of functioning (QLQ-C30) and closely similar in terms of symptoms (QLQ-H&N35). Only for the domains Role and Emotional of the QLQ-C30 did the Autonomous group do better. In the Autonomous group, perception of role in daily life did not change

Table III. Pre-surgical motor evaluation of patients who completed the study.

Motor test	Side	Score (unless otherwise stated)	Autonomous group (n = 25)	Physio group (n = 25)	p value
Passive arm abduction (degrees)	Right	< 180	0 (-)	1 (4%)	0.31
		180	25 (100%)	24 (96%)	
	Left	< 180	1 (4%)	0 (-)	0.31
		180	24 (96)	25 (100%)	
Arm strength (MRC scale)	Right	< 5	3 (12.5%)	5 (20%)	0.48
		5	21 (87.5%)	20 (80%)	
		Unknown	1	-	
	Left	< 5	2 (8.3%)	4 (16%)	0.41
		5	22 (91.7%)	21 (84%)	
		Unknown	1	-	
Head rotation (degrees)	Right	Median (range)	72 (60-80)	70 (60-82)	0.55
	Left	Median (range)	70 (50-80)	70 (60-78)	0.78

Table IV. Clarity of brochure, NSAIDS consumption and compliance with exercise programme.

		Autonomous group (n = 25)	Physio group (n = 25)	p value
Exercises clearly described in brochure	Yes (%)	25 (100)	25 (100)	1*
NSAIDS post-surgery	Yes (%)	8 (32)	12 (48)	0.25*
No. of days on NSAIDS	Median (range)	3.5 (2-30)	7 (3-60)	0.10**
No of exercises per week	Median (range)	14 (0-21)†	14 (0-21)†	0.28**

** Chi-square test; ** Non-parametric Wilcoxon test; † 2 and 0 patients in Autonomous and Physio group respectively, never performed.*

Table V. Pain at baseline (pre-surgery) and two months post-surgery as assessed by 10-point VAS scale.

		Autonomous group (n = 25)	Physio group (n = 25)	p value
Before surgery	Median (range)	0 (0-7)	0 (0-7)	0.95
Two months after surgery	Median (range)	0 (0-5)	0 (0-8)	
Change	Median (range)	-7 (0-4)	-3 (0-6)	0.26*

**Medians compared by non-parametric Wilcoxon test.*

post-operatively, but deteriorated in the Physio group (p = 0.026). Similarly, emotional functioning improved post-operatively (+14) in the Autonomous group, but did not change in the Physio group (p = 0.035). Global Health Status (quality of life) was similar in the two groups, although median scores were higher (p = 0.08) in the Autonomous group. Arm function, determined from items 1 and 5-7 of QLQ-C30, was worse at the two month post-operative examination from baseline in both groups. The deterioration was numerically greater in the Physio group (-17 *vs.* -8; p = 0.07).

Table VI. Primary outcomes: recovery of arm mobility, arm strength and neck mobility at two months.

	Unilateral or bilateral	Autonomous group (n = 25)	Physio group (n = 25)	p (univariable)*	p (multi-variable)**
≥ 90% recovery of passive abduction of arm	Unilateral (n = 36)	14/15 (93%)	19/21 (90%)	0.76	0.61#
	Bilateral (n = 14)	9/10 (90%)	4/4 (100%)	0.51	-
	All	23/25 (92%)	23/25 (92%)	1.0	0.88
100% recovery of arm strength	Unilateral (n = 36)	7/15 (47%)	6/21 (29%)	0.27	0.23#
	Bilateral (n = 14)	1/10 (10%)	1/4 (25.0%)	0.47	0.31#
	All	8/25 (33%)	7/25 (28%)	0.76	0.47
≥ 90% recovery of head rotation†	All	11/25 (44%)	15/25 (60%)	0.26	0.46
Composite endpoint: good motor recovery		5 (20.0%)	5 (20.0%)	1.0	0.64††

** Wald chi-square; ** Wald chi-square – adjusted for side of dissection, sex and age; # unilateral* vs. *unilateral – adjusted for side of dissection, sex and age; † Left and right rotation recovery; †† OR (95%CI) = 1.64 (0.30-7.2).*

Table VII. Pre-operative and two-month post-operative quality of life, functional status, including arm functioning, and head and neck symptoms as assessed by QLQ-C30 and QLQ-H&N35.

		Autonomous group (n = 25) Median score† (IQR**)	Physio group (n = 25) Median score† (IQR**)	p value*
QLQ-C30				
Global Health Status§	Pre-surgery	75 (50-83)	67 (58-83)	
	Post surgery	75 (66-83)	67 (41-83)	
	Delta#	4 (-8, 16)	4 (-17, 8)	0.08
QLQ-C30 functional scales				
Physical functioning	Pre-surgery	100 (93-100)	100 (93-100)	
	Post surgery	93 (80-100)	87 (83-93)	
	Delta#	-7 (-17, 0)	-7 (-13, 0)	0.42
Role functioning	Pre-surgery	100 (100-100)	100 (100-100)	
	Post surgery	100 (83-100)	83 (42-100)	
	Delta#	0 (-17, 0)	-17 (-50, 0)	**0.026**
Emotional functioning	Pre-surgery	83 (67-92)	75 (67-92)	
	Post surgery	100 (83-100)	83 (62-100)	
	Delta#	14 (0, 25)	0 (-17, 17)	**0.035**
Cognitive functioning	Pre-surgery	100 (83-100)	100 (83-100)	
	Post surgery	100 (100-100)	100 (83-100)	
	Delta#	0 (0, 8)	0 (-17, 0)	0.15
Social functioning	Pre-surgery	100 (100-100)	100 (100-100)	
	Post surgery	100 (67-100)	100 (58-100)	
	Delta#	0 (-17, 0)	0 (-33, 0)	0.35
Arm functioning§§	Pre-surgery	100 (100-100)	100 (92-100)	
	Post surgery	87.5 (75-100)	83 (54-92)	
	Delta#	-8 (-21, 0)	-17 (-33, -8)	0.07
QLQ-H&N35 symptom scales				
Pain	Pre-surgery	12 (4-33)	8 (0-17)	
	Post surgery	8 (0-17)	4 (0-25)	
	Delta#	8 (-8, 25)	0 (-8, 8)	0.51
Swallowing	Pre-surgery	0 (0-17)	0 (0-17)	
	Post surgery	8 (8-37)	8 (0-17)	
	Delta#	-8 (-17, 0)	0 (-8, 0)	0.51
Problems with senses	Pre-surgery	0 (0-17)	0 (0-17)	
	Post surgery	8 (8-37)	8 (0-17)	
	Delta#	-8 (-17, 0)	0 (-8, 0)	0.51
Speech problems	Pre-surgery	11 (0-22)	11 (0-33)	
	Post surgery	6 (0-22)	22 (0-33)	
	Delta#	0 (-11, 0)	0 (-22, 11)	0.67
Trouble with social eating	Pre-surgery	8 (0-25)	0 (0-8)	
	Post surgery	12 (4-25)	8 (0-17)	
	Delta#	0 (-8, 17)	0 (0, 0)	0.53
Trouble with social contact	Pre-surgery	0 (0-10)	0 (0-0)	
	Post surgery	0 (0-7)	0 (0-13)	
	Delta#	0 (-7, 0)	0 (-13, 0)	0.27
Less sexuality	Pre-surgery	0 (0-33)	0 (0-0)	
	Post surgery	0 (0-33)	0 (0-33)	
	Delta#	0 (0, 33)	0 (0, 0)	0.25

** Wilcoxon rank sum test; † Range of scores 0 to 100; high scores on QLQ-C30 (including Global Health Status) indicate good functioning (good quality of life); high scores on QLQ-H&N35 indicate more severe symptoms; ** interquartile range; § Based on questions 29 and 30 of QLQ-C30; # Median (with IQR) of difference between post- and pre-surgery; §§ Based on questions 1, 5, 6 and 7 of QLQ-C30.*

Discussion

We found that at two months after surgery, only 20% of patients in both groups had attained the primary composite endpoint of good motor/mobility recovery (Table VI). In addition, Global Health Status, functional scale scores (including the composite assessing arm functioning) and head and neck symptoms were generally worse than before surgery, again in both groups (Table VII). These findings suggest that two months is too short a time to evaluate motor and functional recovery, particularly since nerve fibre regeneration is not complete by two months [15 44].

The second major finding is that there were very few significant differences between the two groups for the variables assessed. We did find, however, that the Autonomous group had significantly better scores in the Role functioning and Emotional functioning domains of QLQ-C30 than the Physio group. We had previously hypothesized that the greater autonomy and responsibility in the Autonomous group might have resulted in better functional recovery, in part by reducing feelings of mistrust, helplessness and resignation [32-39]. However, the present data do not provide support for this hypothesis. Lack of support for this hypothesis is also due to a lack of study power to demonstrate either the equivalence of the interventions or the superiority of one of them. This is because our aim was simply to recruit a sufficient number of patients to perform an exploratory study, particularly in view of the expected problems with early lost patients (confirmed by the fact that only about 50% of those enrolled preoperatively completed the study).

Our other supposition was that early mobilization after surgery would avoid the development of secondary complications such as joint fibrosis and secondary adhesive capsulitis. Published data suggest this is the case [10 22 23 30]. Our findings at the two-month post-surgery evaluation showed that 92% of patients in both groups had recovered ≥ 90% passive abduction arm movement (Table VI). This is an encouraging finding, even though only 44% in the Autonomous group and 60% in Physio group had recovered ≥ 90% of head rotation, and gives grounds to hope that at follow-up evaluation after one year, few patients will have developed secondary complications.

With regard to shoulder and neck pain (Table V) at the two-month follow-up, both groups reported pain levels similar to those at pre-surgery, suggesting that early physiotherapy may help to reduce post-operative pain.

The study of Salerno [10] is the only one, to our knowledge, to investigate the utility of a clearly-specified physiotherapy protocol on pain and shoulder disability after lateral neck dissection. In that study, intervention started 15-30 days after surgery and six months after surgery patients who received the physiotherapy intervention had better arm and shoulder mobility and less pain than those who did not receive physiotherapy. The Authors concluded that pain reduction and early recovery of passive mobilization by physiotherapy were important for the long-term preservation of shoulder, and neck function, since once the complete range of passive motion is achieved, active mobility will recover spontaneously if there is no irreversible nerve damage.

In most of our patients (46/50), level V lymph nodes were resected, and in these patients adverse effects on the shoulder are more common that in more conservative neck dissections that do not remove level V nodes [53]. Radical neck dissection is associated with even greater disability and pain [15 21 42 53 54] since the spinal accessory nerve is sacrificed [55]. However, none of our patients underwent radical neck dissection.

There are several limitations to our study. First it was not randomized. This choice was necessitated by the fact that many of our patients came from distant parts of Italy, and it would have been impossible for them to attend the weekly physiotherapy sessions, particularly since many were also undergoing radiotherapy (at a local facility); these patients were assigned to the Autonomous group, and some even failed to attend the two-month follow-up because of difficulties in travelling. We deliberately restricted the frequency of physiotherapy sessions in the Physio group to ensure that as many patients as possible would attend regularly. The attrition rate of about 50% was expected, not simply because post-surgical complications are fairly common in the patients but because they were recruited before surgery when the treatment programme was still liable to change, as shown in Table I. Clearly, the two-month follow-up was too short, although our aim was to evaluate outcomes at two months; we also intend to assess definitive outcomes at least one year after surgery.

The strong points of our study are that we investigated reproducible protocols (with timing and methods clearly stated), and that the home exercises required no equipment.

In conclusion, our results suggest that early regular exercises performed at home are effective in recovering mobility after lateral neck dissection. They may also help to minimize pain, since it was reduced to pre-operative levels at two months. The therapist-guided sessions (Physio group) appeared to have no beneficial effect, or at least had the same effect as the pre-operative instruction session with the physiotherapist (Autonomous group) in stimulating patients to perform home exercises effectively. Thus, encouraging patients to do their exercises autonomously – to take charge of their own rehabilitation – seems to offer the advantage of saving on resources with no adverse effect on rehabilitation.

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References

1 Shah JP, Patel SG. *Head and neck surgery and oncology*. 3rd ed. Maryland Heights, Missouri: Mosby; 2003. 736 p.

2 Robbins KT, Medina JE, Wolfe GT, et al. *Standardizing neck dissection terminology. Official report of the Academy's Committee for Head and Neck Surgery and Oncology*. Arch Otolaryngol Head Neck Surg 1991;117:601-5.

3 Deganello A, Gitti G, Meccariello G *Effectiveness and pitfalls of elective neck dissection in N0 laryngeal cancer.* Acta

Otorhinolaryngol Ital 2011;31:216-21.

4 Manola M, Aversa C, Moscillo L *Status of level IIb lymph nodes of the neck in squamous cell carcinoma of the oral tongue in patients who underwent modified radical neck dissection and lymph node sentinel biopsy.* Acta Otorhinolaryngol Ital 2011;31:130-4.

5 Antonio JK, Santini S, Politi D *Sentinel lymph node biopsy in squamous cell carcinoma of the head and neck: 10 years of experience*. Acta Otorhinolaryngol Ital 2012;32:18-25.

6 Sigler BA. *Nursing care for head and neck tumor patients*. In: Thawley SE, Panje WR, Batsakik JG, et al., editors. *Comprehensive management of head and neck tumors.* Vol 1. 2nd ed. Philadelphia, PA: Saunders; 1999: p. 59-78.

7 Chaplin JM, Morton RP. *A prospective, longitudinal study of pain in head and neck cancer patients.* Head Neck 1999;21:531-7.

8 Smullen JL, Lejeune FE. *Complications of neck dissection*. J La State Med Soc 1999;151:544-7.

9 Shah S, Har-El G, Rosenfeld RM. *Short-term and long-term quality of life after neck dissection*. Head Neck 2001;23:954-61.

10 Salerno G., Cavaliere M., Foglia A. *The 11th nerve syndrome in functional neck dissection*. Laryngoscope 2002;112:1299-307.

11 Rigual NR, Wiseman SM. *Neck dissection: current concepts and future directions*. Surg Oncol Clin N Am 2004;13:151-66.

12 Herring D, King AI, Connelly M. *New rehabilitation concepts in management of radical neck dissection syndrome*. A clinical report. Phys Ther 1987;67:1095-9.

13 Patten C, Hillel AD. *The 11th nerve syndrome. Accessory nerve palsy or adhesive capsulitis?* Arch Otolaryngol Head Neck Surg 1993;119:215-20.

14 Carenfelt C, Eliasson K. *Occurrence, duration and prognosis of unexpected accessory nerve paresis in radical neck dissection*. Acta Otolaryngol 1980;90:470-3.

15 Remmler D, Byers R, Scheetz J, et al *A prospective study of shoulder disability resulting from radical and modified neck dissections*. Head Neck Surg 1986;8:280-6.

16 Fialka V, Vinzenz K. *Investigations into shoulder function after radical neck dissection.* J Craniomaxillofac Surg 1988;16:143-7.

17 Soo KC, Guiloff RJ, Oh A, et al. *Innervation of the trapezius muscle: a study in patients undergoing neck dissections.* Head Neck 1990;12:488-95.

18 Capodaglio P, Strada MR, Grilli C. *La valutazione della capacità lavorativa con gli arti superiori dopo intervento di svuotamento latero-cervicale.* G Ital Med Lav Ergon 1998;20:39-43.

19 Kuntz AL, Weymuller EA Jr. *Impact of Neck Dissection on Quality of life.* Laryngoscope 1999;109:1334-8.

20 Laska T, Hanning K. *Physical therapy for spinal accessory nerve injury complicated by adhesive capsulitis*. Phys Ther 2001;81:937-44.

21 Erisen L, Basel B, Irdesel J *Shoulder function after accessory nerve-sparing neck dissections.* Head Neck 2004;26:967-71.

22 Cappiello J, Piazza C, Nicolai P. *The spinal accessory nerve in head and neck surgery*. Curr Opin Otolaryngol Head Neck Surg 2007;15:107-11.

23 Lauchlan DT, McCaul JA, McCarron T. *Neck dissection and the clinical appearance of post-operative shoulder disability: the post-operative role of physiotherapy*. Eur J Cancer Care 2008;17:542-8.

24 Johnson EW, Aseff JN, Saunders W. *Physical treatment of pain and weakness following radical neck dissection.* Ohio State Med J 1978;74:711-4.

25 Nowak P, Parzuchowski J, Jacobs JR. *Effects of combined modality therapy of head and neck carcinoma on shoulder and head mobility*. J Surg Oncol 1989;41:143-7.

26 Van Wilgen CP, Dijkstra PU, Nauta JM, et al. *Shoulder pain and disability in daily life, following supraomohyoid neck dissection: a pilot study.* J Craniomaxillofac Surg 2003;31:183-6.

27 Guru K, Manoor UK, Supe SS. *A comprehensive review of head and neck cancer rehabilitation: physical therapy perspectives.* Indian J Palliat Care 2012;18(2):87-97.

28 Carvalho AP, Vital FM, Soares BG. *Exercise interventions for shoulder dysfunction in patients treated for head and neck cancer.* Cochrane Database Syst Rev. 2012 Apr 18;4:CD008693. Urgency Medicine, Universidade Federal de São Paulo, São Paulo, Brazil.

29 McNeely ML, Parliament M, Courneya KS. *A pilot study of a randomized controlled trial to evaluate the effects of progressive resistance exercise training on shoulder dysfunction caused by spinal accessory neurapraxia/neurectomy in head and neck cancer survivors*. Head Neck 2004; 26:518-30.

30 McNeely ML, Parliament MB, Seikaly H. *Effect of exercise on upper extremity pain and dysfunction in head and neck cancer survivors*. Cancer 2008;113:214-22.

31 World Health Organization. *The World Health Report 2000:Health Systems: Improving Performance.* Geneva: WHO; 2000. 215 p.

32 Street RL Jr, Voigt B. *Patient participation deciding breast cancer treatment and subsequent quality of life.* Med Decis Making 1997;17:298-306.

33 Lev EL, Daley KM, Conner NE, et al. *An intervention to increase quality of life and self-care self-efficacy and decrease symptoms in breast cancer patients.* Sch Inq Nurs Pract 2001;15:277-94.

34 Trento M, Passera P, Bajardi M. *Lifestyle intervention by group care prevents deterioration of Type II diabetes: a 4-year randomized controlled clinical trial.* Diabetologia 2002;45:1231-9.

35 Doorenbos A, Given B, Given C, et al. *Reducing symptom limitations: a cognitive behavioral intervention randomized trial*. Psychooncology 2005;14:574-84.

36 Jean Wiese H, Boethel C, Phillips B, et al. *CPAP compliance: video education may help!* Sleep Med 2005;6:171-4.

37 Gucciardi E, Demelo M, Lee RN, et al. *Assessment of two culturally competent diabetes education methods: individual vs. individual plus group education in Canadian Portuguese adults with type 2 diabetes*. Ethn Health 2007;12:163-87.

38 Kinnane N, Thompson L. *Evaluation of the addition of video-based education for patients receiving standard pre-chemotherapy education*. Eur J Cancer Care (Engl) 2008;17:328-39.

39 Wise M, Han JY, Shaw B, et al. *Effects of using online narrative and didactic information on healthcare participation for breast cancer patients*. Patient Educ Couns 2008;70:348-56.

[40] Norkin CC, White DJ. *Measurement of Joint Motion: A guide to goniometry.* Philadelphia: F.A. Davis Company; 2003. 404 p.

[41] Haribhakti VV, Kavarana NM, Tibrewala AN. *Oral cavity reconstruction: an objective assessment of function.* Head Neck 1993;15:119-24.

[42] Dijkstra PU, van Wilgen PC, Buijs RP. *Incidence of shoulder pain after neck dissection: a clinical explorative study for risk factors*. Head Neck 2001;23:947-53.

[43] Adler SS, Beckers D, Buck M. *La facilitaciòn neuromuscular proprioceptiva en la pràtica.* Guia ilustrada 2nd ed. Mèdica Panamericana; 2002. 425 p.

[44] Köybasioglu A, Tokcaer AB, Uslu S, et al. *Accessory nerve function after modified radical and lateral neck dissections*. Laryngoscope 2000;110:73-7.

[45] Kottke FJ, Stillwel GK, Lehmann JF. *Trattato di terapia fisica e Riabilitazione*. Roma: Verduci Editore;1987. 1200 p.

[46] Boccardi S, Lissoni A. *Cinesiologia 2*. Roma: Società Editrice Universo; 1985. 422 p.

[47] MRC Medical Research Council. *Aids to the examination of the peripheral nervous system, Memorandum no. 45*. London: Her Majesty's Stationery Office;1976. 61 p.

[48] Marchese C, Cristalli G, Pichi B. *Italian cross-cultural adaptation and validation of three different scales for the evaluation of shoulder pain and dysfunction after neck dissection: University of California - Los Angeles (UCLA) Shoulder Scale, Shoulder Pain and Disability Index (SPADI) and Simple Shoulder Test (SST).* Acta Otorhinolaryngol Ital 2012;32:12-7.

[49] Bascioni R, Giorgi F, Esperide B, et al. *Quality of life (QOL) assessment with EORTC QLQ-C30 in daily clinical practice*. J Clin Oncol 2005;23(Suppl):8205.

[50] Aaronson NK, Ahmedzai S, Bergman B. *The European Organization for Research and Treatment of Cancer QLQ-C30: a quality-of-life instrument for use in international clinical trials in oncology*. J Natl Cancer Inst 1993;85:365-76.

[51] Zotti P, Lugli D, Vaccher E, V, et al. *The EORTC quality of life questionnaire-head and neck 35 in Italian laryngectomized patients*. Qual Life Res 2001;9:1147-53.

[52] Fayers PM, Aaronson NK, Bjordal K, et al. *On behalf of the EORTC Quality of life group. The EORTC QLQ-C30 Scoring Manual*. 3rd Ed. Bruxelles: European Organization for research and treatment of cancer; 2001. 85p.

[53] Terrell JE, Welsh DE, Bradford CR. *Pain, quality of life, and spinal accessory nerve status after neck dissection*. Laryngoscope 2000;110:620-6.

[54] Short SO, Kaplan JN, Laramore GE, et al. *Shoulder pain and function after neck dissection with or without preservation of the spinal accessory nerve.* Am J Surg 1984;148:478-82.

[55] Cheng PT, Hao SP, Lin YH, et al. *Objective comparison of shoulder dysfunction after three neck dissection techniques*. Ann Otol Rhinol Laryngol 2000;109:761-6.

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