

An evaluation of functional outcomes (speech, swallowing) in patients attending speech pathology after head and neck cancer treatment(s): results and analysis at 12 months post-intervention

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Abstract

We have earlier reported establishing a computerized database to audit functional outcomes in patients who underwent head and neck cancer treatment in Victoria, Australia and attended speech pathology services from April 1997–April 1999. This paper presents the statistical analyses and results from this study.

Speech pathologists collected, prospectively, functional outcome data on 293 patients who underwent head and neck cancer treatment, and sent these for analysis to La Trobe University. Clinician and patient assessments of outcomes: speech, swallowing, activity, pain, employment, health, QOL status were made.

Initial data on 293 patients were collected and data on mortality and morbidity were compiled at three, six and 12 months post-treatment. Within twelve months, 74 patients had died. Three, six and/or 12-month follow-up data was available on 219 patients, with both clinician and patient assessments of status completed. The status forms are presented as appendices to this paper. Complete status forms on 179 patients at 12 months were obtained.

This clinical audit of functional outcomes represents the first study of this kind, collecting data from speech pathologists and patients in a multi-centre study of patients with head and neck cancer. We present data to demonstrate optimal recovery of function at six months, such that this may represent a good reference point for reporting and comparison of functional outcomes.

Key words: Database; Speech; Deglutition; Outcome Assessment; Head and Neck Neoplasms

Introduction

We earlier reported^{1,2} the setting up of a speech pathology multi-centred database to audit prospectively the outcomes of speech and swallowing in people who have undergone treatment for head and neck cancer in a systematic and coordinated way.

Our earlier papers described the problems in multi-centre data collection in Melbourne, Australia, and the difficulties in long-term prospective data collection from the head and neck cancer population. We gave the design and early results and discussed the challenges in developing a useful tool for data collection and clinical audit.

We now report on data from the cohort of 293 patients whose data were submitted by speech pathologists from nine distal clinics offering a service to head and neck (H and N) cancer patients. These data were collected centrally at La Trobe University between April 1997–April 2000 with accrual of new patients completed in 1999. The aim of this paper is

to report on these patients' mortality and morbidity (swallowing and speech outcomes) at 12 months' post-treatment.

For ease of reporting, cancer treatment for the total cohort is presented first and then the patients were divided into the following four groups for separate analysis and results; total laryngectomy patients; oral cancer; pharyngeal cancer; and laryngeal (non-laryngectomy) cancer patients. The discussion pertains to the full cohort study.

Materials and methods

These were described in full in an earlier paper, published in the *Journal of Laryngology and Otology* in 2000.²

Subjects

Between April 1997–April 1999, data from 293 patients (64 female; 229 male) attending eight

TABLE I
SUBJECT DEMOGRAPHICS

Group	N	Gender		Age		New cancer	Recurr/ Residual	Mortality	
		Male	Female	M	SD	n	n	%	n
Laryngeal	23	18	5	63.4	11.8	14	9	13	3
Laryngeal with laryngectomy	76	63	13	65.1	10.3	53	23	20	15
Pharyngeal	51	36	15	61.1	11.7	28	23	43	22
Pharyngeal with laryngectomy	21	19	2	64.5	9.1	18	3	48	10
Oral	85	61	24	60.2	14.1	59	26	18	15
Other (previous laryngectomy n = 22 or site other or unknown n = 15)	37	32	5	64.1	12.6	5	32	24	9
Total	293	229	64	62.5	12.1	177	116	25	74

different centres in Victoria were collected by speech pathologists. One hundred and sixteen patients had been seen previously but re-presented to speech pathology with ‘new’ problems following a recurrence resulting in further cancer treatment. One hundred and seventy-seven were referred having had no previous cancer treatment. Of these latter patients, 71 underwent total laryngectomy; 59 were treated for oral cancer, 28 had pharyngeal cancer, 14 had laryngeal cancer but did not undergo laryngectomy, and five subjects had cancer in other sites (see Table I).

We report the mortality data on all subjects and then the speech and swallowing outcomes across these ‘new cancer’ groups in this paper. In our earlier papers^{1,2} we stated, after 12 months, that the data represented an overall referral rate to speech pathology services of 16 per cent of patients who had head and neck cancer (a notifiable disease) in Victoria. This relatively low percentage has remained essentially the same over the life of this database study (two years with one year follow-up).

Method

A collaborative computerized database of patients who underwent head and neck cancer treatment in Victoria was established in the School of Human Communication Sciences, La Trobe University. Patient demographic and status data (regarding speech; swallowing; Quality of Life, or QOL) were collected in speech pathology clinics from patients immediately post-cancer treatment. The status forms (see Appendices) were re-administered, completed and submitted to the database manager (MS) at La Trobe University at three, six and 12 months post-treatment.

Results and data analysis

Overall cohort: new cancers

Table II shows the breakdown of all new cancer patients (n = 177) into their site of primary tumour: oral, pharyngeal and laryngeal (non-laryngectomy) cancer and, separately, those laryngeal cancer patients who underwent total laryngectomy.

Treatment consisted of radiotherapy, surgery, chemotherapy or multi-modality treatment as shown in Table III.

Mortality: overall cohort. Figure 1 shows the overall mortality across all patients at 12 months, divided into cancer sites, treatment and showing these patients who presented with new cancers (n = 177) as a proportion of the overall cancer group (n = 293).

Laryngectomy subjects

There were 99 patients who underwent either total laryngectomy or extended laryngectomy (laryngo-pharyngectomy) and attended speech pathology in Victoria between April 1997–April 1999. There were 84 males (85 per cent) and 15 females. Thirty-nine patients had additional neck nodal disease; 50 had no nodes and 10 were unrecorded. Of these patients, 28 had received prior cancer treatment and 71 presented having had no prior disease (‘new’ patients).

Mortality. In examining only the new cancer patients in our study (n = 71), 12 patients (17 per cent) who underwent total laryngectomy died within 12 months of entering the study. Of the overall cohort, 26 of the 99 died within 12 months (26 per cent). The size of tumour did not seem to be predictive of mortality although, as only five patients had T₂ tumours, the rest being T₃ or T₄, this comment might be re-

TABLE II
PATIENTS WITH NO PREVIOUS CANCER TREATMENT: CANCER SITE AND T STAGE

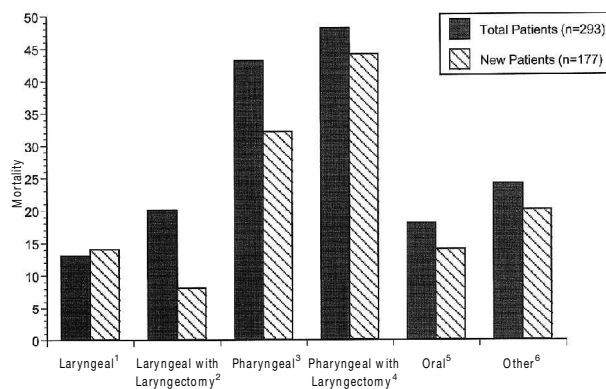
Cancer site	T Stage					Total
	T ₁	T ₂	T ₃	T ₄	NA	
Laryngeal	6	2	3	1	2	14
Laryngeal with laryngectomy	0	5	25	21	2	53
Pharyngeal	2	10	7	9	0	28
Pharyngeal with laryngectomy	0	0	7	9	2	18
Oral	4	19	19	15	2	59
Other/Unknown	0	2	0	3	0	5
Total	12	38	61	58	8	177

TABLE III
PATIENTS WITH NO PREVIOUS CANCER TREATMENT: TREATMENT BY SITE AND T STAGE

Cancer Site	Treatment	T stage				X*	Total
		T ₁	T ₂	T ₃	T ₄		
Laryngeal	Radiotherapy	4	1	1	0	0	6
	Radiotherapy and chemotherapy	0	0	1	0	0	1
	Surgery	2	1	1	0	2	6
	Surgery and radiotherapy	0	0	0	1	0	1
	Total	6	2	3	1	2	14
Laryngeal with laryngectomy	Surgery	0	2	7	8	0	17
	Surgery and radiotherapy	0	2	15	12	2	31
	Surgery and chemotherapy	0	1	0	0	0	1
	Surgery, radiotherapy and chemotherapy	0	0	3	1	0	4
	Total	0	5	25	21	2	53
Pharyngeal	Radiotherapy	1	1	3	0	0	5
	Radiotherapy and chemotherapy	0	0	2	0	0	2
	Surgery	0	1	0	1	0	2
	Surgery and radiotherapy	1	8	2	8	0	19
	Surgery, radiotherapy and chemotherapy	0	0	0	0	0	0
Total	2	10	7	9	0	28	
Pharyngeal with laryngectomy	Surgery	0	0	3	3	0	6
	Surgery and radiotherapy	0	0	3	6	2	11
	Surgery, radiotherapy and chemotherapy	0	0	1	0	0	1
	Total	0	0	7	9	2	18
Oral	Radiotherapy	0	1	0	1	0	2
	Surgery	3	11	5	9	0	28
	Surgery and radiotherapy	0	7	14	5	2	28
	Surgery, radiotherapy and chemotherapy	1	0	0	0	0	1
	Total	4	19	19	15	2	59

*X for missing or unknown T stage

examined statistically with larger numbers of patients. Mortality data (with the reason for death) for the total group of laryngectomy patients were as follows: 14 (54 per cent) were cancer-related (either recurrence or further extension of original cancer); five (19 per cent) were medically-related and seven (27 per cent) patients from rural Victoria died for reasons unknown to the researchers.



¹Total (deaths = 3, N = 23), New patients (deaths = 2, N = 14)

²Total (deaths = 15, N = 76), New patients (deaths = 4, N = 53)

³Total (deaths = 22, N = 51), New patients (deaths = 9, N = 28)

⁴Total (deaths = 10, N = 21), New patients (deaths = 8, N = 18)

⁵Total (deaths = 15, N = 85), New patients (deaths = 8, N = 59)

⁶Total (deaths = 9, N = 37), New patients (deaths = 1, N = 5)

FIG. 1
Cancer sites/treatment.

Factors associated with mortality were examined using chi-square analysis. There were six variables of interest including site of tumour, T-stage of tumour, N-stage, current treatment modality, clear excision margins and presence or absence of previous treatments. There were three factors that were found to be associated with mortality in laryngectomy patients including site, $\chi^2(1) = 7.01, p < .01$; presence or absence of previous cancer treatments, $\chi^2(1) = 11.36, p < .01$; and whether the surgeon achieved clear excision margins, $\chi^2(2) = 11.03, p < .01$. Mortality was greatest for patients who had hypopharyngeal tumours (50 per cent mortality as compared to 19.7 per cent for laryngeal tumour patients); for patients who had had previous treatments (50 per cent mortality as compared to 16.9 per cent for new cancer diagnosis); and for patients with a lack of clear excision margins (58.3 per cent mortality as compared to 16.7 per cent for clear excision).

Surgical practices in Victoria

The 99 total laryngectomy procedures in Victoria, which occurred between 1997–1999, were conducted by 29 different ENT surgeons (see Table V). This table shows that nine (31 per cent) of the surgeons in Victoria performed only one total laryngectomy or extended laryngo-pharyngectomy during the two

TABLE IV
MORTALITY STATISTICS FOR LARYNGECTOMY PATIENTS WITHIN 12 MONTHS OF TREATMENT

Factor		Survived		Died		Total N
		n	%	n	%	
Site of Lesion**	Larynx	61	80.3	15	19.7	76
	Hypopharynx	9	50.0	9	50	18
	Total	70	74.5	24	25.5	94
Previous cancer treatment***	No previous cancer treatment	59	83.1	12	16.9	71
	Previous cancer treatment	14	50.0	14	50	28
	Total	73	73.7	26	26.3	99
Clear excision margins**	Clear excision margins	55	83.3	11	16.7	66
	No clear excision	5	41.7	7	58.3	12
	Total	60	76.9	18	23.1	78

**Pearson Chi-square $p < .01$

***Pearson Chi-square $p < .001$

years 1997–99. The mean number of procedures performed by all surgeons was 3.5 but perhaps only one surgeon could be said to have an expertise in the area, having performed 15 such procedures in the two years examined.³

Surgical voice restoration

Surgical voice restoration, also called tracheo-oesophageal puncture (TEP) or the Blom-Singer procedure, has been well established and is generally viewed as a credible procedure with a low operative complication rate^{4–6} and evidently high success rate for communication post-laryngectomy.^{7–9} The procedure was developed by Drs Blom and Singer in 1979 and, in developed countries, most surgeons in head and neck cancer units nowadays use primary TEP (i.e. the procedure is undertaken at the time of total laryngectomy) as a chosen mode of communication rehabilitation. The number of primary procedures performed on patients who underwent laryngectomy and laryngopharyngectomy procedures in Victoria is shown below.

It can be seen there is a large variability in surgical voice rehabilitation practices in Victoria, ranging from Units (6, 8, 9) where primary punctures are undertaken on 100 per cent of laryngectomees, to units where none is undertaken (7).³ It is of note that Units 6, 8, 9 were dealing with relatively small numbers of patients compared to larger centres (1, 2, 3) where correspondingly more laryngectomies were undertaken but a smaller percentage of primary punctures offered. Overall, 63 per cent of laryngectomees in Victoria were given primary TEP.

TABLE V
NUMBER OF PROCEDURES PERFORMED BY SURGEONS IN VICTORIA BETWEEN 1977–1999

No. of procedures performed by surgeon	Number of Surgeons
1	9
2	5
3	7
5	4
6	1
8	1
10	1
15	1
Total	29

Functional outcomes post-laryngectomy

Communication. At 12 months post-treatment, the modes of communication used by laryngectomees were examined, assessing only those who had primary or secondary TEP. Fifty-six patients were still alive in this group. Of these, two (four per cent) were using oesophageal speech alone; 13 (25 per cent) were using electrolarynges (EL) alone; 21 (41 per cent) were using TEP speech alone, with 10 (20 per cent) using both TEP and electrolarynges and five (10 per cent) using no speech, just writing and gesture. Data were missing for five subjects.

Successful TEP and others. Outcomes at 12 months for surviving laryngectomy patients who had primary TEP speech were contrasted with those who did not undergo the procedure (i.e. non-TEP), using a series of Mann-Whitney U tests. The patients who underwent TEP and who had good fluent speech had significantly better outcomes than those who did not have the procedure with respect to general health ($U = 300.5$, $p < .01$); patient-rated speech ($U = 267.0$, $p < .001$); speech handicap ($U = 345.5$, $p < .05$); clinician expectation of outcome ($U = 351.0$, $p < .05$), performance status ($U = 372.0$, $p < .05$), speech intelligibility ($U = 281.5$, $p < .001$) and swallowing status ($U = 365.5$, $p < .05$).

Outcomes by treatment

Different types of cancer treatment were given to these laryngectomy patients. Two patients underwent chemotherapy and surgery. Across the remain-

TABLE VI
PRIMARY TEP PRACTICES BY UNIT 1997–1999

Unit	Number of procedures	Number of primary punctures	Percentage of primary punctures
1	19	15	79
2	23	9	39
3	12	7	58
4	17	14	82
5	13	6	46
6	4	4	100
7	4	0	0
8	6	6	100
9	1	1	100
Total	99	62	63

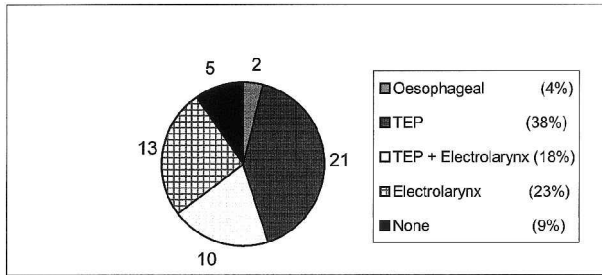


FIG. 2

Mode of voice at 12 months of laryngectomy survivors who have had a primary or secondary TEP. $n = 56^*$

*there are 5 missing values

ing 97 patients, three discrete types of treatment regime could be identified: surgery alone ($n = 24$); previous radiotherapy, current surgery ($n = 21$); surgery and post-operative radiotherapy ($n = 52$).

To determine whether the reason for new laryngectomy patients having a worse outcome from surgery and radiotherapy, when compared to those who had only surgery, might have been due to the severity of disease (as represented by tumour or T size), a Fisher's exact test was conducted. Surgery alone was compared to surgery and other treatments (radiotherapy or chemotherapy/radiotherapy) and T stages were categorized into two categories – mild (T1/T2) and severe (T3/T4) for patients who had undergone laryngectomy (this includes patients with either laryngeal or pharyngeal cancers). For the patients who had surgery, 91.3 per cent ($n = 21$, $N = 23$) had either T3/T4 sized tumours. This trend was replicated for the patients who had surgery and other treatments (93.2 per cent, $n = 41$, $N = 44$). There was no significant relationship between

severity of disease and choice of treatment, $p = .783$. Hence, in these cases, treatment was not acting as a proxy for disease severity.

Morbidity: swallowing, comparative QOL. Statistical analyses were conducted using the Mann-Whitney U test to determine whether there were differences in outcomes among subjects who had new cancers, comparing those who had surgery only *versus* those who had surgery and post-operative radiotherapy. These analyses were run separately immediately post-operatively, and at three months, six months, and 12 months post-treatment. Immediately post-operatively, patients who had surgery followed by radiotherapy experienced significantly less pain ($U = 138.0$, $p < 0.05$), and fewer respiration difficulties ($U = 129.0$, $p < 0.01$), than those patients who had surgery only. At three months, the surgery and radiotherapy group had a significantly better performance status than patients who had surgery alone ($U = 164.5$, $p < 0.01$). At six months, the surgery and radiotherapy patients had better respiration ($U = 173.5$, $p < 0.05$); better performance status ($U = 156.5$, $p < 0.05$) as compared to patients who had had only surgery. By 12 months post-treatment, differences across treatment methods were not significantly different. This may have been due to the reduction in the numbers of survivors and missing data.

Assessment of the changes in outcomes for the 73 surviving laryngectomy patients was examined for the 12-month period. Wilcoxon signed ranks test was employed to compare outcome data at three to six months, six to 12 months, and three to 12 months. The most noticeable changes in outcomes occurred between three to six months post-surgery. Significant improvements between this time period were noted

TABLE VII
ALL LARYNGECTOMIES: COMPARISON OF TEP AND NON-TEP SPEAKERS STATUS AT 12 MONTHS^a

Outcome measure ^b	No TEP speech				TEP speech			
	M	Mdn	(SD)	n	M	Mdn	(SD)	n
Activity**	3.7	4.0	(0.8)	35	4.3	4.0	(0.8)	28
Recreation*	3.7	4.0	(0.8)	35	4.2	4.2	(0.7)	28
Appearance*	2.5	3.0	(0.7)	35	2.8	3.0	(0.5)	28
Health**	2.7	3.0	(0.9)	35	3.3	3.5	(0.9)	28
Speech (patient rated)***	2.5	3.0	(0.7)	35	3.1	3.0	(0.4)	28
Taste*	2.8	3.0	(1.0)	34	3.3	3.0	(0.7)	28
Normal saliva consistency*	0.8	1.0	(0.4)	35	0.5	0.5	(0.5)	30
Patient expectation**	2.9	3.0	(1.1)	35	3.7	4.0	(0.7)	27
OQOL*	3.6	4.0	(1.2)	35	4.2	4.0	(1.0)	28
Speech pathology regime*	1.1	1.0	(0.7)	33	1.7	1.0	(1.0)	30
Swallowing impairment*	3.3	4.0	(1.6)	34	4.2	4.0	(0.7)	30
Speech disability*	3.6	4.0	(1.3)	34	4.3	5.0	(1.0)	30
Handicap*	3.3	4.0	(1.2)	34	3.9	4.0	(0.9)	30
Clinician expectation*	2.9	3.0	(1.1)	34	3.5	3.5	(0.7)	30
WHO performance status*	2.9	3.0	(0.8)	34	3.3	3.0	(0.7)	30
Intelligibility***	3.1	3.0	(1.0)	34	3.8	4.0	(0.5)	30
Swallowing (clinician rated)*	7.2	8.0	(1.8)	34	8.1	8.0	(0.8)	30
Use of AAC***	0.4	0.0	(0.5)	35	0.0	0.0	(0.2)	30

^aSurviving laryngectomees at 12 months, $n = 73$. Note that 8 cases were lost to follow-up at 12 months and there were some cases with incomplete responses. Hence the variation in n 's in the above Table.

^bSee appendices

*Mann-Whitney U $p < .05$

**Mann-Whitney U $p < .01$

***Mann-Whitney U $p < .001$

TABLE VIII
CHANGES IN OUTCOMES BETWEEN 3, 6 AND 12 MONTHS POST-CANCER TREATMENT IN LARYNGECTOMY SURVIVORS

Outcome measure ^a	3 months				6 months				12 months			
	n	M	Mdn	SD	n	M	Mdn	SD	n	M	Mdn	SD
CQOL	52	2.4	2.0	0.9	55	2.9	3.0	1.0	64	2.8	3.0	1.1
Intelligibility	52	3.0	3.0	1.0	54	3.5	4.0	0.7	64	3.4	4.0	0.9
Speech disability	53	3.3	3.0	1.4	54	4.0	4.0	1.2	64	3.9	4.0	1.2
Handicap	52	3.2	4.0	1.2	54	3.7	4.0	0.9	64	3.6	4.0	1.1
Distress	52	3.8	4.0	1.2	54	4.1	4.0	0.9	63	4.0	4.0	1.1

^aSee appendix

for speech disability ($Z = -3.5, p < .01$), speech handicap ($Z = -2.7, p < .01$), distress ($Z = -2.1, p < .05$), intelligibility ($Z = -3.4, p < .01$), and comparative quality of life ($Z = -3.1, p < .01$). Between three to 12 months, there were significant improvements in pain ($Z = -2.6, p < .01$), swallowing ($Z = -2.5, p < .05$), speech intelligibility ($Z = -3.6, p < .01$), and speech disability ($Z = -3.5, p < .001$). These results are interesting, especially as between three to six months changes in pain and swallowing were not significant. Between six to 12 months swallowing continued to improve ($Z = -2.1, p < .05$). It would seem that slow, steady improvement in swallowing over (as much as) 12 months might be expected in these patients; whereas for other aspects measured, status was optimally changed by six months. There was no significant change between the six to 12-month period.

At 12 months, the patients who had undergone a laryngectomy due to hypopharyngeal cancer had significantly worse outcomes than those who had undergone laryngectomy due to laryngeal cancer. Their status was worse in all of the following areas: activity ($U = 112.0, p < .05$), health ($U = 108.0, p < .05$), speech impairment ($U = 111.5, p < .01$), speech disability ($U = 109.0, p < .01$), handicap ($U = 117.5, p < .05$), and performance ($U = -123.5, p < .05$). Of the patients who were using an electro-larynx, those who had hypopharyngeal cancer had a significantly worse level of communicative ability ($U = 49.0, p < .05$) than the other laryngectomees in the study.

Subjects with oral cancers

There were 85 patients who had oral cancers and presented to speech pathologists during this study; 61 male (72 per cent) and 24 female. Neck nodes were positive in 37 patients. Fifty-nine patients presented with new cancers and 26 had recurrence(s).

Mortality

Of the 85 patients in total who presented with oral cancers in this study, 15 (18 per cent) died within 12 months. There was no significant relationship between having previous cancer treatment and mortality. Eight of 59 (14 per cent) died in the 'new' cancer group and seven of 26 (27 per cent) died in the group who had undergone previous cancer treatment.

Chi-square analysis indicated that there was a significant relationship between the presence of positive neck nodes and mortality $\chi^2 = 7.62, p < .01$. In the subjects with no nodes, three out of 40 (7.5 per cent) died, whereas in the subjects with positive neck nodes, 12 of 37 (32 per cent) died.

Age was also related to mortality $\chi^2 = 7.69, p < .01$ but only for those patients who presented with new oral cancers. More deaths occurred among younger than older patients. Under 50 years of age, five of the 14 (36 per cent) patients died within 12 months of treatment whereas, in the over 50 age group, only three of 45 (seven per cent) subjects died.

Treatment

In examining the regimes for cancer treatment in the 59 patients who presented with new oral cancers, three had either no T-stage recorded, or missing N stage. Of the remaining 56 patients, those who had a T stage less than T₃ and no positive neck nodes (n = 13), 12 (21 per cent) were treated with surgery alone, and one patient (one per cent) had surgery followed by chemo-radiotherapy. Of the patients who had either T₃ or T₄ stage tumour or neck nodes (n = 43), 16 (29 per cent) had surgery only, two (four per cent) had radiotherapy only and 25 (45 per cent) had a combination of surgery followed by radiotherapy.

In the overall group of 85 (i.e. new and recurrent) oral cancer patients, 45 (53 per cent) had surgery alone; five (six per cent) had radiotherapy; 33 (39 per

TABLE IX
COMPARISON OF OUTCOMES AFTER LARYNGECTOMY RESULTING FROM HYPOPHARYNGEAL AND LARYNGEAL CANCERS

Outcome measure	Larynx				Hypopharynx			
	n	M	Mdn	SD	n	M	Mdn	SD
Activity	53	4.08	4.00	0.85	8	3.38	3.50	0.74
Health	53	3.06	3.00	0.99	8	2.25	2.00	0.71
Speech impairment	53	2.06	2.00	1.23	9	1.00	1.00	1.00
Speech disability	53	4.08	4.00	1.09	9	2.78	3.00	1.39
Performance	53	3.11	3.00	0.78	9	2.44	3.00	0.73
Handicap	53	3.68	4.00	1.01	9	2.56	3.00	1.42

TABLE X
SURVIVAL STATISTICS FOR PATIENTS WITH ORAL CANCER WITHIN 12 MONTHS OF TREATMENT

Factor		Survived		Died		Total count
		n	%	n	%	
Presence of neck nodes**	Nodes	25	68	12	32	37
	No nodes	37	93	3	7	40
	Total	62	81	15	19	77

**Pearson chi-square $p < .01$

In 8 patients presence of neck nodes was not known.

cent) had surgery followed by radiotherapy; two (two per cent) had other treatment. Seventeen (20 per cent) of these patients required additional cancer treatment during the time of this study (eight of whom had neck dissection).

Functional outcomes post-treatment: Small vs large tumours

In considering the whole group ($n = 85$), and dividing the patients into those with small (T_1/T_2) and those with large (T_3/T_4) oral cancers, perhaps unsurprisingly, there was a significantly worse outcome for patients having treatment for larger tumours, when compared to those with smaller tumours. This was manifest in the following areas: post-surgery, the patients with T_3 , T_4 tumours reported significantly more saliva problems ($U = 242.5$, $p < .01$) than those with T_1 , T_2 ; significantly more husky voices, which was significant at both three ($U = 166.0$; $p < .01$) and six ($U = 128.0$; $p < .01$) months post-treatment. Patients' laryngeal voices were less audible post-radiotherapy ($U = 35.5$; $p < .05$) and this was maintained at six months ($U = 199.5$; $p < .05$). Considering the patients who presented with new oral cancers ($n = 59$), 28 (47 per cent) of the group were treated with surgery alone and 28 (47 per cent) with surgery followed by radiotherapy, with three (five per cent) patients undergoing chemo/radiotherapy.

Outcomes by treatment

Communication

At three and at 12 months post-treatment, patients who had new cancers and underwent surgery and radiotherapy had significantly worse outcomes than those who underwent surgery alone in terms of speech impairment, intelligibility, and speech disability. These remained significantly worse at 12 months.

Swallowing, comparative QOL

At both three and six month time points, those subjects who underwent surgery followed by radiotherapy reported experiencing significantly less taste than those who underwent surgery alone. Patients' swallowing abilities were significantly worse at three, six and 12 months if they had undergone surgery and radiotherapy rather than surgery alone. In subjects who underwent surgery alone, immediately post-surgery, from data available, 10 (24 per cent) patients required tube feeding, whereas for patients who then had radiotherapy, immediately post-radiotherapy, 11 (46 per cent) required tube feeding. Oral nutrition at 12 months was significantly worse in the surgery and radiotherapy group compared to the surgery alone cohort. At 12 months, six (35 per cent) patients were still tube feeding after surgery and radiotherapy treatment, compared with only one (three per cent) who had surgery alone.

TABLE XI

COMPARISON OF OUTCOMES BY TREATMENT AT 12 MONTHS: PATIENTS WITH NEW ORAL CANCER HAVING SURGERY ALONE VS SURGERY AND RADIOOTHERAPY

Outcome measure ^a	Surgery only				Surgery and radiotherapy			
	n	M	Mdn	SD	n	M	Mdn	SD
Taste**	20	3.3	3.0	0.9	13	2.3	3.0	1.0
Swallowing (patient rating)*	20	3.6	4.0	0.6	13	2.5	2.0	1.1
Swallowing impairment***	22	4.0	4.0	1.2	13	2.1	2.0	1.7
Swallowing (clinician rating)***	22	7.7	8.0	1.5	13	5.1	6.0	2.3
Oral nutrition*	22	1.0	1.0	0.2	13	0.5	1.0	0.5
Speech impairment**	22	4.0	4.0	0.8	13	2.9	3.0	1.3
Speech disability*	22	4.7	5.0	0.6	13	3.8	4.0	1.4
Intelligibility*	22	4.1	4.0	0.6	13	3.2	4.0	1.0

^aSee appendix

Mann-Whitney U test

* $p < .05$

** $p < .01$

*** $p < .001$

TABLE XII
SURVIVAL STATISTICS FOR PATIENTS WITH PHARYNGEAL CANCER WITHIN 12 MONTHS OF TREATMENT

Factor		Survived		Died		Total count
		n	%	n	%	
Presence of neck nodes*	No nodes and T ₁ or T ₂	11	85	2	15	13
	Nodes or T ₃ or T ₄	16	47	18	53	34
	Total	27	57	20	43	47

*Pearson chi-square $p < .05$

4 patients had T stage or nodes status missing.

In examining the total cohort of survivors ($n = 70$), their comparative quality of life, or C-QOL, was better at 12 months compared with three months ($Z = -2.15$; $p < .05$). No other parameter showed differences between three and 12 months.

Subjects with pharyngeal cancer without total laryngectomy

There were 51 patients who had pharyngeal cancer and presented to speech pathologists during this study. Of these, 36 (71 per cent) were male and 15 female. Neck nodes were positive in 16 of 48 patients (33 per cent) with three patients' nodal status unrecorded.

Mortality

Of the 51 patients who presented with pharyngeal cancer, 22 (43 per cent) died within 12 months. Of the total, 23 had recurrent cancer and 28 were patients with new cancer. In the group with new cancer, nine patients (32 per cent) died within 12 months. The predictor variables for mortality were examined using the Chi square test. The only variables to reach statistical significance for predicting mortality across these patients were, perhaps not surprisingly, the combination of the presence of positive neck nodes and having a tumour size of T₃ or T₄.

Positive nodes alone or T stage alone did not reach statistical significance; however, with a larger cohort of subjects, this finding might be re-examined.

The second predictor variable in this study was age ($\chi^2 = 12.60$; $p < .01$). None of the 11 patients under 50 years died during the study, whereas 22 of 40 (55 per cent) of those over 50 died.

Treatment

Overall, 18 (35 per cent) patients had surgery alone; seven (14 per cent) had radiotherapy alone; 21 (41 per cent) had surgery and radiotherapy and five (10 per cent) patients had mixed modality treatment. In considering solely the patients with new cancers, ($n = 28$); radiotherapy alone was the treatment for five (18 per cent); surgery alone was offered to two (seven per cent); surgery and radiotherapy to 19 (68 per cent) and mixed modality treatment (chemo-radiotherapy) to two (seven per cent) patients. Only two patients had neither current nor previous radiotherapy.

Outcomes by treatment

Once divided into differing treatment groups, the numbers of survivors within each became too small for statistical analysis. Since there were only 29 survivors overall and no difference in mortality was demonstrated between the two groups (i.e. those patients with new and those with recurrent cancers), the total cohort was grouped to examine functional outcomes over time. Immediately post-surgery, many of the patients who were planned for post-operative radiotherapy had data missing (e.g. 11 out of 28 patients did not have their immediate post-surgery status recorded), although these patients were then recorded post-radiotherapy. In view of this, a comparison was made of the following: those patients who had surgery alone and those who had surgery and radiotherapy; those who had surgery alone and those who had radiotherapy alone; those who had radiotherapy alone and those who had surgery followed by radiotherapy.

Communication

The group treated with surgery alone compared to the group treated by radiotherapy alone demonstrated significantly worse outcomes for both respiration ($U = 4.0$, $p < .05$) and for speech impairment ($U = 4.0$, $p < .05$) at six months. Speech intelligibility was significantly worse at both six ($U = 2.0$, $p < .01$) and 12 months ($U = 1.5$, $p < .05$). Speech disability was significantly worse in the surgery alone group at three months ($U = 2.5$, $p < .01$). Four (27 per cent) subjects immediately post-surgery were at a level of 'occasional communication or less', whereas only one (seven per cent) subject post-radiotherapy had such poor communication. All subjects had consistent communication by three months post-treatment.

Swallowing, comparative QOL

Immediately post-treatment, six (40 per cent) patients who had surgery alone needed tube feeding whereas seven (50 per cent) patients who underwent surgery and radiotherapy required tube feeding post-treatment. By three months, four (33 per cent) patients who underwent surgery alone still required tube feeding, as did seven (27 per cent) of those who underwent surgery and radiotherapy. By 12 months, three (50 per cent) still required tube feeding in the surgery alone group compared to two (17 per cent) in the surgery and radiotherapy group.

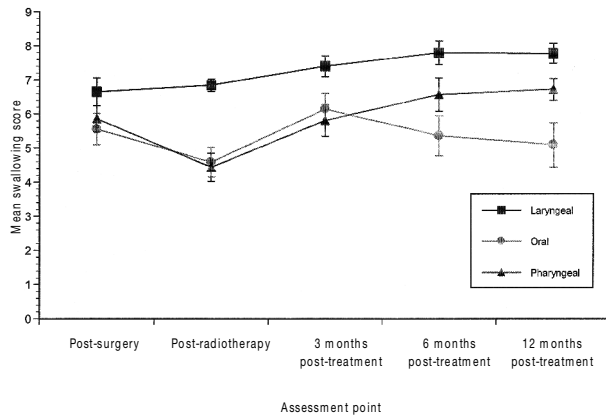


FIG. 3

Mean swallowing outcomes (+ OR - 1 SE) by treatment/cancer sites.

Subjects with laryngeal cancers (without laryngectomy)

This was a small number of patients who presented to speech pathologists. Twenty-three patients in total were represented, 18 (78 per cent) male and five (19 per cent) female. Three patients (13 per cent) died within the time scale of this study. Fourteen patients (61 per cent) had new cancers and nine were recurrent. Neck nodes were present in three of the patients (14 per cent) and, across patients, treatments varied: 14 (61 per cent) had surgery alone; six (26 per cent) had radiotherapy alone; three (13 per cent) had mixed modality (surgery/radiotherapy and chemo/radiotherapy) treatment. Tumour size varied, with $T_1 = 7$; $T_2 = 7$; $T_3 = 4$; $T_4 = 1$ and four patients were not staged. In view of the small numbers, statistical examination of functional outcomes in this group was not possible.

Swallowing impairment across different cancer sites

The effect of radiotherapy on swallowing across different cancer sites was examined (see Figure 3). The subjects with laryngeal cancer had higher (i.e. better) swallowing scores than either those in the oral or the pharyngeal cancer groups across all time points examined. Interestingly, radiotherapy seemed to impact less on the laryngeal cancer group in terms of swallowing dysfunction than on either of the other two. Radiotherapy had a marked effect by reducing swallowing ability in both subjects with oral and with pharyngeal cancer whereas, in the subjects with laryngeal cancer, the effect was negligible.

Discussion

One of the difficulties in collecting data in a study such as this is the turnover of staff in modern healthcare practice, from which this study was not immune. Of the eight speech pathologists (working over nine cancer units) who began this project, six had left by the study's end, three years' later. Although most staff were replaced over time, one centre withdrew from the study (so did not

contribute data from new subjects after 20 months), citing that they were 'too short-staffed' to complete and submit the status data forms. Follow-up data for patients who were registered from this centre were therefore not able to be obtained and accounts for much of the missing data sets.

The variability in treatment modalities in this study made it difficult to statistically analyse results. Our hope for providing an evidence base for better outcomes by comparing differing treatments was naive, but nevertheless this study offers some indications for treatment.

In terms of mortality after laryngectomy, it is not surprising that prior cancer treatment and clear surgical excision margins were associated with survival, and previous published studies have reported worse mortality for patients with hypopharyngeal cancer¹⁰ and worse swallowing morbidity in these patients pre-treatment.¹¹ We were, however, surprised that there was a statistically significant difference between functional outcomes in subjects who had undergone laryngectomy from hypopharyngeal cancer when compared with cancers from other (laryngeal) sites. These outcome differences were statistically significantly different (i.e. worse for laryngectomy from hypopharyngeal cancer) across most functions examined.

Rates of success for speech from surgical voice restoration after laryngectomy were disappointingly low. With success rates for speech acquisition reported from 75–90 per cent^{7–9} from world's best practice, the outcome for subjects in this study was very low, with only 38 per cent laryngectomees using the Blom-Singer procedure alone successfully. In examining reasons for this, the turnover of specialist speech pathology staff (six of eight involved in this data collection study left during the three years of this study) may be an important factor, with new clinicians needing to develop skills and expertise in this area.

The number of surgeons involved (Table VI) and the wide variability in surgical practice (Table VII) may also be factors to consider. It has been reported elsewhere that many laryngectomees in Victoria do not have the option of primary surgical voice restoration.³ In an endeavour to address variations in treatment practices in UK, the British Association of Otolaryngologists-Head and Neck surgeons (1998)¹² produced the consensus document *Effective Head and Neck Cancer Management* which gives guidelines and standards and perhaps a similar document in Australia would merit consideration.

A report published by Cancer services in Wales (1996)¹³ recommended that ... 'surgeons undertaking head and neck cancer surgery should be restricting their surgery to the anatomical region in which they have been primarily trained and in which they would normally carry out the majority of their operating in the course of the normal working day.' It can be seen from Table VI that most ENT surgeons in Victoria cannot be said to specialise in laryngectomy and/or extended laryngo-pharyngectomy surgery.

An unexpected finding from this study was that patients who underwent TEP and had good fluent speech were also statistically significantly better across other outcome measures from those who did not (Table VII). One would not expect TEP to be acting as an indicator of other health outcomes. From this finding, it would be tempting to conclude that TEP has a beneficial effect. However, caution should be exercised, as it may be the converse – that these surgeons selected patients who had potentially good medical/surgical outcome and operated on these with a TEP. This needs further investigation to confirm this suggestion.

In terms of patients with oral cancer, in this study there was an association between both age (young) and the presence of positive neck nodes and mortality. At three and 12 months post-treatment, worse functional outcomes were reported in those patients who had new cancers and multi-modal treatment (surgery/radiotherapy) than in those who had surgery alone (see Table III). Swallowing outcomes were worse at 12 months for subjects who had multi-modal treatment compared to those who had surgery alone, with 35 per cent subjects still being tube fed at 12 months after surgery and radiotherapy against three per cent after surgery alone. Radiotherapy seemed to have a more adverse immediate affect on swallowing in people with oral and pharyngeal cancers than those with laryngeal cancers. The former two groups experienced more severe dysphagia from treatment.

Conclusions

This work represents the first multi-centre data collection by speech pathologists from patients to detail functional outcomes after head and neck cancer treatment. The study audited cancer practice and functional outcomes of patients treated in Victoria, some of which need further investigation. Speech and swallowing outcomes for all patients were optimal at six months' post-treatment, such that this would seem to be a good reference time point at which to report and compare functional results.

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Appendix 1

Functional Outcomes / Head and Neck Cancer Database

Patient Status

Patient Initials: _____

Date of birth: (dd/mm/yy) __/__/__

Postcode: _____

Date: __/__/__

This section of the form is to be completed by the PATIENT with the assistance of the clinician**Clinician's Initials:** _____**Hospital:** **Assessment:**

- 0 = Pre therapy
 1 = Post surgery (at discharge or 14 days post surgery)
 3 = Post DXT/chemotherapy
 4 = Three months post therapy
 5 = Six months post therapy
 6 = Twelve months post therapy

 Activity:

- 1 = I am usually in bed or chair and don't leave home
 2 = I don't go out because I don't have the strength
 3 = I am often tired and have slowed down my activities although I still get out
 4 = There are times when I can't keep up my old pace, but not often
 5 = I am as active as I have ever been
 6 = Not applicable

 Recreation:

- 1 = I can't do anything enjoyable
 2 = There are severe limitations to what I can do, mostly I sit at home and watch TV
 3 = There are many times when I wish I could get out more but I'm not up to it
 4 = There are a few things I can't do but I still get out and enjoy life
 5 = There are no limitations to recreation at home or away from home
 6 = Not applicable

 Employment:

- 1 = I am unemployed
 2 = I am retired, due to cancer treatment
 3 = I have only occasional employment due to cancer treatment
 4 = I have only occasional employment by choice
 5 = I am retired, not related to cancer treatment
 6 = I have a part time but permanent job
 7 = I work full time

 Appearance:

- 1 = I feel significantly disfigured and limit my activities due to my appearance
 2 = My appearance bothers me but I remain active
 3 = The change in my appearance is minor
 4 = There is no change in my appearance

 Health:

- 1 = Poor
 2 = Fair
 3 = Good
 4 = Very Good
 5 = Excellent

 Pain:

- 1 = I have severe pain not controlled by medication
 2 = I have severe pain controlled only by narcotics
 3 = I have moderate pain requiring regular medication (codeine or non-narcotic)
 4 = There is mild pain not needing medication
 5 = I have no pain

 Speech:

- 1 = I cannot be understood
 2 = Only my family and friends can understand me
 3 = I have difficulty saying some words, but most people can understand me
 4 = My speech is the same as always

 Taste:

- 1 = I cannot taste any foods
 2 = I can taste some foods
 3 = I can taste most foods normally
 4 = I can taste food normally

 Saliva:

- 1 = I have no saliva
 2 = I have too little saliva
 3 = I have a normal amount of saliva
 4 = I have too much saliva

Functional Outcomes / Head and Neck Cancer Database

Patient Status

Patient Initials: _____
 Postcode: _____

Date of birth: (dd/mm/yy) __/__/__
 Date: __/__/__

Saliva consistency:
 Is the saliva of normal consistency (Y/N)?

Swallowing:
 1 = Cannot swallow anything
 2 = Can swallow liquids or vitamised foods
 3 = Can swallow only soft food
 4 = Normal swallow

Voice:
 1 = No voice
 2 = Husky or hoarse voice most of the time
 3 = Husky or hoarse voice occasionally
 4 = Normal voice

Respiration:
 1 = Need oxygen supplement
 2 = Always short of breath, even at rest
 3 = Frequently short of breath after exertion
 4 = Occasionally short of breath
 5 = No difficulties

Is your current condition:
 1 = Much worse than expected
 2 = Worse than expected
 3 = In line with your expectations
 4 = Better than expected
 5 = Much better than expected

Overall quality of life:
 Including factors such as family, friends, spirituality and personal leisure activities
 1 = Very poor
 2 = Poor
 3 = Fair
 4 = Good
 5 = Very Good
 6 = Excellent

Comparative quality of life:
 Compared to one year prior to diagnosis of your illness, how would you rate your quality of life in general now?
 1 = Much worse now
 2 = Worse now
 3 = About the same
 4 = Better now
 5 = Much better now

Current smoking status:
 Average number of cigarettes etc. per day

Alcohol intake:
 Average number of standard drinks per day
 eg glass of wine, glass of beer
 0 = None
 1 = 1 - 2 standard drinks
 2 = 3 - 4 standard drinks
 3 = 5 - 6 standard drinks
 4 = > 6 standard drinks

Usual type of alcoholic beverage consumed:
 0 = None
 1 = Spirits
 2 = Beer
 3 = Wine
 4 = Combination

Additional comments:

Appendix 2

Functional Outcomes / Head and Neck Cancer Database

Clinician Status

Patient Initials: _____
 Postcode: _____

Date of birth: (dd/mm/yy) ___/___/___
 Date: ___/___/___

Speech pathology regime:
 1 = Daily
 2 = Weekly
 3 = Monthly
 4 = Other, *specify*.....

Total number of speech pathology visits:
 (since last Status Form completed)

Disease status: (*circle numbers*)
 1 = No evidence of disease
 2 = Residual disease, primary site
 3 = Residual disease, neck nodes
 4 = Recurrent disease, primary site
 5 = Recurrent disease, neck nodes
 6 = Distant metastasis

Does the patient have a severe late complication of treatment at this visit?
 0 = No
 1 = Yes, *specify*.....

Has disease progressed since the last assessment?
 0 = No
 1 = Yes

Has the patient received further treatment since the last assessment?
 0 = No
 1 = Yes, *please complete the relevant treatment form*

Has the patient developed a new primary cancer since the last assessment?
 0 = No
 1 = Yes, *please complete the diagnosis form*

Impairment:

Swallowing **Speech**

0 = Severe level of impairment
 1 = Severe/moderate level of impairment with some variability
 2 = Moderate impairment
 3 = Moderate/slight level of impairment
 4 = Slight level of impairment
 5 = No impairment

Disability:

0 = No functional communication
 1 = Occasional functional communication with a trained 'listener'
 2 = Occasional functional communication with others
 3 = Consistent level of functional communication with trained key persons
 4 = Functions well with occasional assistance
 5 = Functional communication

Handicap:

0 = Low self worth (esteem/value by others)
 1 = Low self worth
 2 = Mostly appropriate self worth and role with immediate family
 3 = No difficulties in familiar settings
 4 = Occasional restrictions/difficulties in some aspects of life
 5 = No difficulties with peer group, work, education or recreation

Distress:

0 = Severe consistent distress - overt and covert
 1 = Severe distress frequently experienced
 2 = Moderate and consistent distress
 3 = Moderate distress frequently experienced
 4 = Mild occasional distress
 5 = No inappropriate distress

Is the patient's condition:

1 = Much worse than expected
 2 = Worse than expected
 3 = In line with expectations
 4 = Better than expected
 5 = Much better than expected

Functional Outcomes / Head and Neck Cancer Database

Clinician Status

Patient Initials: _____
 Postcode: _____

Date of birth: (dd/mm/yy) ___/___/___
 Date: ___/___/___

WHO performance status:

0 = Completely disabled, cannot carry out any self-care , totally confined to bed or chair
 1 = Capable of limited self care, confined to bed or chair more than 50% of waking hours
 2 = Ambulatory and capable of all self-care but unable to carry out any work, up and about more than 50% of waking hours
 3 = Restricted in physical activity but ambulatory and able to carry out light work
 4 = Able to carry out all normal activity without restriction

Intelligibility score:

1 = Unintelligible
 2 = Intelligible when the context is known (50%)
 3 = Intelligible when the context is known (80%)
 4 = Speech changed but 100% intelligible
 5 = Normal, no change to speech

Swallowing:

No oral feeding
 1 = Aspiration of secretions, patient rarely swallows
 2 = Secretions managed with suction and/or medication, patient swallows reflexively

Needs tube feeding
 3 = Tube feeding
 4 = Supplemental tube feeding

Dietary consistency changes
 5 = Liquefied diet
 6 = Vitamised diet
 7 = Soft diet

Early eating problems
 8 = Mild abnormality

Normal eating habits
 9 = Normal swallowing

Primary nutrition status:

1 = Parenteral /TPN
 2 = Percutaneous endoscopic gastromy
 3 = Nasogastric tube
 4 = Oral
 5 = Other

Laryngeal voice:

0 = Not applicable
 1 = Inaudible
 2 = Audible in quiet surroundings
 3 = Audible always

Oesophageal voice:

0 = Not applicable
 1 = No usable speech / involuntary sounds
 2 = Single words
 3 = Short phrases
 4 = Good fluent speech

Tracheo Oesophageal Puncture:

0 = Not applicable
 1 = No usable speech / involuntary sounds
 2 = Single words
 3 = Short phrases
 4 = Good fluent speech

Electrolarynx:

0 = Not applicable
 1 = No usable speech / involuntary sounds
 2 = Single words
 3 = Short phrases
 4 = Good fluent speech

Uses AAC system
 Such as gestures, computer etc. (Y/N)

Any other major illnesses/ complications:
 Give details.....

Comments: