Informing patient choice and service planning in Surgical Voice Restoration: Valve usage over three years in a UK Head and Neck Cancer Unit

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Abstract

Objectives: To determine the number, reasons and costs of SVR-related tracheoesophageal valve attendances over 36 months at a head and neck oncology unit.

Methods: We recorded demographic, medical and valve related details from all patient contacts, including +/-self-changer, +/-urgent appointment, modifications required and costs of prostheses.

Results: Over three years 99 patients underwent 970 valve changes. Main reasons for changes were central leakage, prophylactic change and self-changed at home. Changes were significantly more frequent in the first 12-months (mean 42 days) compared to longstanding patients (mean 109.96). Intervals between changes were unpredictable; no predictive factors reached statistical significance. Mean expenditure on valves was £966.63 per week (including VAT and in-house customisation).

Conclusion: Valve lifespan is comparable to outcomes in similar units despite more pre-emptive and patient-led changes and more comprehensive data inclusion. Investigations are needed into how patient satisfaction and costs relate to valve selection and units' service delivery models.

Keywords: total laryngectomy; surgical voice restoration; alaryngeal voice; voice prosthesis; head and neck oncology.

Introduction

UK head and neck cancer guidelines[1] recommend offering primary Surgical Voice Restoration (SVR) (at the time of laryngectomy) to all patients and to consider incorporating oesophageal voice and electrolarynx into rehabilitation of communication. SLT professional policy advises SVR suitability discussions should be MDT based and SVR should not be discounted without full discussion with patient and carer taking place[2]. However, there exists limited research to enable clinicians to help patients weigh up potential risks, benefits and commitments in order to make an informed choice about SVR[3-4]. Even uneventful SVR obligates patients to lifelong, unplanned hospital visits when valve mechanisms fail at the end of their lifespan. Complications, including those requiring urgent hospital assistance, are relatively common. Investigation of this attendance burden for patients is important as concerns about urgent SVR service provision were raised by the National Association of Laryngectomy Clubs (NALC) and led to a survey of English SVR units[5]. Previous studies[3,6-8] looking at the profile of planned and unplanned visits and the reasons for these have been restricted in scope, methods and generalisability across settings. All recommend further investigation.

Furthermore, the issue of costs, of valves and related items and estimated costs to services of supporting SVR has been similarly restricted[9-10]. Such factors are important for the commissioning of adequate staffing and procurement of equipment to meet this need.

We report comprehensive data for all total laryngectomy patient attendances linked to SVR over 36-months at one UK Regional Head and Neck Cancer Unit. This article focuses on attendances for valve related issues and usage to address the following questions:

a) How many valve changes were necessary over the three-year study period?

b) What were the reasons for valve changes?

c) What number of urgent and elective appointments were required?

d) What valves and modifications were required?

e) What was the total cost of valves over the three-year study period?

f) What speech-language therapy (SLT) resources were required to meet this need?

Materials and Methods

Ethics

The South East Scotland Research Ethics Service advised that this project was classified as service evaluation hence ethical review to conduct this study was not required. The Caldicott Guardian at NHS Lothian gave approval for use of the database and specified an information governance protocol.

Participants

All patients in the study were cared for by the South East of Scotland surgical service for head and neck cancer network serving a population of 1.4 million across four health administrations. The study followed two groups of patients over a 36-month period:

a) all existing SVR patients already on the current caseload at the start of the study period

b) all new SVR patients during the study period.

These are referred to as “existing” and “new” to differentiate the two groups.

This study reports data for all total laryngectomy patient attendances linked to Surgical Voice Restoration (SVR) over 36-months at one UK Head and Neck Cancer Unit. A dedicated database and data entry form captured all valve changes. Fields covered prosthesis use and biographical data (Table 1). Definitions of the reasons for change were pre-agreed between SLT team members with training provided (by K McLachlan) to facilitate consensus-implementation.

Table 1 about here

Every SVR-related attendance was documented in the database by the SLT immediately post contact, with the exception of self (patient)-led valve changes. These were entered retrospectively from SLT case-notes. Any patients who died during the 36-month collection period were retained in the study. Biographical data was imported from information routinely collected by surgeons. Some patients underwent surgery prior to the initiation of this ENT protocol (n=21). For these cases biographical data was inputted retrospectively from SLT notes.

Model of Service Delivery

Four specialist SLTs provide all SVR troubleshooting services to all South East of Scotland unit patients (round trip of up to 200 miles/6-hours return drive). Some distant patients are transferred to local services for simple routine valve changes with return to the regional service if required. Twenty-eight elective and urgent appointments are provided Monday to Friday, with unused slots reallocated to other head and neck oncology in/out-patients. Two urgent daily slots are always retained for patients to book by telephone; walk-in requests are discouraged. Consultant Surgeon advice is available via telephone or after SLT triage, via the joint ENT/SLT monthly SVR clinic; two videofluoroscopy +/- botulinum toxin slots per week and FEES (available as needed) support complex patients.

Patients receive counselling about the implications of SVR from the SLT and surgeon and are offered primary SVR unless listed for pharyngectomy (total or partial) with free flap reconstruction or if judged unable to self-manage a prosthesis due to cognitive, mental health, alcohol or physical impairments. Pectoralis major flaps (routinely used in post-chemoradiotherapy salvage surgery) do not preclude primary SVR. Secondary SVR is considered 3-months post-surgery/post-adjuvant radiotherapy for those capable of valve care with confirmed voicing on videofluoroscopic air insufflation test. Patients and carers must demonstrate adequate competence in assessing and managing central leak and valve dislodgement following a training programme and generally self-manage out with SLT hours.

Nurses and doctors on the ENT ward provide a limited evening/weekend service, following SLT-designed algorithms until troubleshooting is available on SLTs' next working day. The algorithm for extruded valves is to fit a catheter into the tracheo-oesophageal puncture (TEP) and discharge home whereas valve leakage involves placing a nasogastric tube and admitting to hospital or, (if feasible) temporarily plugging the valve lumen and discharge home.

Prophylactic valve changes are offered for those living at a distance, and/or lacking transport, who are less compliant with valve leakage or deemed at risk of aspiration pneumonia requiring hospital admission. SLTs initiate contact (telephone or letter) if patients have not attended for 12 months but if they do not respond to the request.to attend the valve remains in situ until they present.

Valve Selection and Protocols

Primary SVR involves initial voice prosthesis placement 24-48 hours after resumption of oral diet. Exdwelling Blom-Singer valves are fitted whenever possible depending on an open tract voicing assessment (duckbill if no strain,16Fr low pressure if strain is present). Blom-Singer Classic Indwelling 16fr valves are rarely required but fitted if there is a risk of extrusion/not managing an exdwelling prosthesis. Patients are supported to retain the exdwelling valve and self-change whenever possible. These valves are continued if exdwelling valve lifespan is >4 weeks or indwelling >6 weeks with consistent, unstrained voicing. The protocol for changing valve type is:

a) Effort for voice – change duckbill to low pressure
b) Early central leak unrelated to candida or spontaneous opening – fit Provox NiD, Blom-Singer Dual valve or Provox Vega
c) Accidental extrusion – switch to indwelling +/- a large oesophageal flange (LEF) in-house custom modification

d) Peripheral leak – change length if appropriate otherwise fit LEF (if Blom-Singer) and loose tracheal washer alone (if Provox), if this does not resolve fit LEF Blom-Singer with tracheal washer, if this fails arrange TEP augmentation
e) Candida unresponsive to medication or non-compliance – fit Blom-Singer Dual valve

Calculation of number and reasons for valve changes

Details of the number of valve changes per person per year during the first 12 months (for new patients) and for subsequent years (new and existing patients) was derived from the database. Time that each prosthesis was in situ was also calculated, and descriptive statistics regarding the number of attendances against each reason for valve change. Total number of attendances was calculated for those classed as elective (prophylactic or patient request) or urgent (all other reasons to attend).

Cost of Resources

Consumables

Costs of all out-patient valves fitted (not purchased as stock) were calculated using Severn Healthcare's catalogue (October 2019) and Atos Medical's UK price list (2019). In-house custom valve modifications were calculated from cost of silicone sheet and adhesive used. As few units undertake in-house custom modification, we calculated an alternative costing of purchasing factory customised valves. The first valve fitting as an in-patient was added as an exdwelling Blom-Singer low pressure.

Speech and Language Therapy sessions

We counted the total number of SVR related attendances over the 36-month period and whether these were urgent or elective (as outlined above). SLT time to modify a voice prosthesis in-house was estimated as 15mins per prosthesis.

Results and analysis

Ninety-nine cases met inclusion criteria for the study (Table 2). Eighty existing SVR patients entered when they attended their first out-patient SVR intervention after 1st August 2015. Nineteen new SVR patients entered the caseload during the 36-month timeframe and joined the database at their first out-patient intervention.

Table 2 about here

There was no statistically significant difference between the proportion of men vs women in the existing vs new groups, nor any significant gender differences by age at surgery ($p = 0.76$), distribution of T stage ($p = 0.92$), N stage ($p = 0.54$), site of surgery ($p = 0.34$), salvage vs primary operation ($p = 0.79$) or type of operation ($p = 0.98$). Subsequent analyses therefore treated females and males as a single group.

The existing group were aged mean 67.98 years (SD 11.08) at the start of the study, the new group mean 63.47 (SD 7.45), a statistically non-significant difference. The existing group was mean 7.22 years (SD 6.34; median 5, IQR 2-12) post-surgery. During the study period twenty individuals deceased in the existing group, three in the new group (proportion difference non-significant, $p = 0.55$). The people who died were older (mean 68.87 years, SD 11.75) than the survivors (mean age 66.56, SD 10.24), but not statistically significantly. The data for deceased cases is included in analyses below unless explicitly stated that it is omitted. Table 3 summarizes main demographic and medical characteristics.

(Table 3 about here)

Comparing the existing vs new groups, there were no statistically significant differences between them by profile of tumour site, surgery type, tumour stage, nor N stage at operation. There was no significant different in the proportion receiving pre- vs post-operation radiotherapy, nor CRT. There was a significantly higher proportion in the new group receiving secondary operations (chi 4.78(1), p = 0.03).

Valve changes

For the cohort (n 99) there were 970 valve changes over the three years (existing n = 797, new n = 173). This represented mean 323.3 changes per annum or 3.32 changes per person per year for the existing group and 3.03 for the new cases. Adjusted for deceased cases, mean total changes per survivor during the study was 11.00 (SD 7.54; median 9, IQR 11, range 1-31), or 3.66 per annum.

During the 12 months after their first valve fitting there were 118 changes in the new group, mean 6.21 per person (SD 2.97; median 6, IQR 4-8; range 1-12), not counting the first post-operative in-patient fitting. The time an individual waited from fitting of the initial valve on the ward until the first out-patient change was mean 41.53 days (SD 43.19; median 35, IQR 13-54, range 0-193).

As the large SDs/IQRs and ranges illustrate, there was considerable inter- and intra-individual variation in number of changes necessary during a given period and the corresponding times in situ. Changes were seldom spread evenly across time for any individual. Comments on this follow below.

We examined for associations of demographic and medical variables with the number of valve changes required. Whilst N and T stage were unsurprisingly strongly correlated with the need for a primary rather than secondary operation and need for pre- and post-operative CRT (all p = <0.001), they did not relate significantly to change totals. The relationship between total valve changes required and N stage (Spearman's r .198, p = 0.066) and pre-operative CRT (r .189, p = 0.062) approached significance. No other variables showed associations even approaching significance.

Time in situ

The mean time in situ for a valve from the first outpatient fitting across the whole cohort across the study period was 102.3 days (SD 81.82; median 75, IQR 46-131). The existing group showed longer mean times between changes (mean 109.96 days, SD 86.14; median 83, IQR 91; range 1-518) than the new group (mean 66.02, SD 47.37; median 52, IQR 47; range 25-239; Mann Whitney <0.001). A factor in this may be the significantly shorter (Mann Whitney <0.001) mean minimum days in situ for the new group (mean 13.63, SD 16.08; existing mean 51.89, SD 69.02), reflecting more frequent changes necessary in the early post-operative phase. Groups did not vary statistically significantly on mean maximum days in situ (existing mean 199.80, SD 131.30; new mean 150.95, SD 98.4).

This difference is emphasized if one looks at the mean time in situ for each valve during the first 12 months post-operation for the new group. Including people who died (n = 3) during this time there were mean 42.17 days in situ (SD 23.31; median 36, IQR 34-52; range 0-115). Excluding people who died the figures are mean days 44.52 (SD 22.78; median 37, IQR 34-54, range 19-115).

There was no statistically significant trend for gaps between changes to become systematically longer or shorter, even though over the study as a whole at a group level, the significant differences between groups (above) for time in situ suggests an overall trend to more prolonged periods between changes as time progresses.

The lack of systematic trends for time in situ over time appears linked to the massive inter- and intra-individual variation for time between changes (range 1-518 days), reflected also in the large SDs/IQRs. Examination of individual cases illustrates that the pattern of time in situ could be highly variable. Periods of relative stability might be followed by a time of frequent changes (see below).

Reasons for valve changes

Table 4 details the reasons for valve changes for all changes recorded across the two groups whilst in the study.

Table 4 about here

To examine whether the relative frequency of reasons for change was similar across groups correlations between the rank-order of reasons for change between groups were analysed. There was no significant correlation between the subgroups when all variables were entered as raw totals. This applied whether self-changes were included or not (with self-changes Spearman's r .588, p = 0.074; without, r 643, p = 0.062).

Correlations between reasons for change across groups based on proportion of each change expressed as a percentage of all changes showed no significant association if self-changes were included (r .573 p = 0.083). When they were excluded the association between rank orders was statistically significant (r .711, p = 0.032) suggesting a main difference between the groups concerned the higher number of self-change procedures in the existing group (rank order in existing group 2/10, new group 7=/10).

In addition to primary reasons for changes there were on occasions secondary reasons. Two related to dislodgement, 11 to secondary peripheral leak and 37 to miscellaneous. These did not significantly alter the rank order or relative proportions of reasons for change Furthermore, 26 washer modifications were necessary, 38 LEF modifications and 3 Provox Xtraflange modifications.

To look for a possible difference in profile of reasons for change early post-operation versus later the pattern of changes for the new group during their first 12 months post-surgery was compared to the profile of the existing group. Table 5 displays the reasons for the 118 changes in the new group during their first 12 months post-operatively. Spearman's rank order correlation based on percentages showed no significant correlation between reasons with self-changes included (r .253, $p = 0.48$) or without self-changes (r .576, $p = 0.10$).

Table 5 about here

The tables for changes give summaries for the different reasons across all cases over the whole study. Examination of specific reasons for change and how these applied to individual cases discloses marked patterns of variability of profile. For example, peripheral leak represents a prominent reason for change. However, for 74 people this was not a reason for change. If one excludes those where peripheral leak happened only once, there were only 10 cases where peripheral leak featured. For some of these cases management of the problem was by a valve change, for others by valve extras. Furthermore, change frequency (time in situ) in such cases could reflect a period of frequent changes until the problem was settled followed by longer periods in situ once fixed (discussed below). Elective attendances (prophylactic or patient request reasons for change) accounted for 21.3% of all appointments for the whole cohort but this varied from 1.77% of those in the first 12 months of SVR compared to 26% for the existing cohort with established SVR.

Valve costs to service

In order to calculate costs, the type of valve inserted at each change was charted. Table 6 details valves employed by the service and their relative proportions across groups. The correlation of frequency of use of the different valves across subgroups was strongly significant (Spearman's r .976, $p = <0.001$).

Table 6 about here

Overall there was no significant difference in the proportion of in-dwelling versus ex-dwelling valves fitted during the study period (n 464 vs n 506; binomial exact, p = 0.188 two tailed). Within the existing group ex-dwelling valves were proportionately more common (binomial exact, p = 0.01 two tailed); the difference within the new group was borderline significant (binomial exact, p = 0.05, two tailed). Chi square indicated significantly different proportions of in- versus ex-dwelling valves across the subgroups (chi 7.91(1), p = 0.005). Binomial testing showed a non-significant difference for indwelling valves (binomial exact p = 0.43, two tailed), but a highly significant difference for ex-dwelling valves across groups (binomial exact p = 0.001, two tailed).

Table 7 details the costs to the service. Over 36-months the total cost of valves purchased, including value added tax (VAT) at 20% was £149,961.48 (mean per annum £49,987.16) of which £100,159.08 was indwelling (n=444) and £49,802.40 exdwelling (n=506).

Table 7 about here

Forty-three patients required a modified valve (range 1-33 placements). The additional expenditure was eleven Provox Xtraflanges (£401.15) (range 1-6 per person), 94 in-house tracheal washers (range 1- 11 per person) and 204 in-house large oesophageal flange modifications (range 1-22 per person). The combined cost of valves and all modifications gave a total consumable expenditure of £125,662.19

(£150,794.63 with VAT). For units who are unable to custom-modify their own valves and must purchase these from the factory the equivalent calculation is represented by £145,098.85 (£174,118.62 with VAT). The addition of nineteen low pressure exdwelling valves to represent the cost of the first placed in-patient valve for the new patients, not recorded on the out-patient database, gives an additional (£1,748 or £2,097.60 with VAT) giving a final figure of £127,410.19 (£152,892.23 with VAT) for this unit or £146,846.85 (£176,216.22 with VAT).

Speech and Language Therapy resources

A total of 802 SLT appointments were required to meet the SVR troubleshooting out-patient requirements of the whole cohort; of these 171 (21.3%) were elective and 631 (78.7%) were urgent. A total of 298 in-house modifications were carried out requiring approximately 15 minutes each or 74.5 hours in total over the 3-year period.

Discussion

This study aimed to provide new information that can be used in counselling patients who are considering SVR and to inform service delivery and commissioning of staff and voice prosthesis resources. Although many studies have investigated the perspective of complication rates[11], no study to date before this current study has captured every reason for SVR-related out-patient attendance with prospectively collected data from a consecutive series of patients. Furthermore, this investigation is the first to report on a service delivery model that includes both a comprehensive prophylactic change option to pre-empt valve leakage and self-changeable valves. Such information would allow patients to make a more informed decision about consenting to SVR and how this may impact on their life in terms of pre-planned versus urgent attendances from lifelong hospital attendances for valve troubleshooting e.g. due to leakage through or around the valve or accidental displacement into the airway. Allowing patients to gauge the commitment of travel burden and cost is pertinent when some UK patients could travel in excess of 50 miles to access valve services[5].

Comparing the findings of this investigation to previous studies is difficult due to methodological differences. Previous studies have been designed to focus on the lifespan of the valve[3,6-8]. These cannot inform patient attendance burden or annual costing of prostheses as they discounted attendances when the valve mechanism was still intact[7] or omitted oedema reduction related size changes occurring within the first 90 days[3] or six months[8]. Further exclusions in previous research include replacements undertaken at other units[3] or for valves that are rarely used, “fitted for developmental study purposes” or removed immediately when incorrectly sized[6]. A focus on total group mean and median valve life allows outliers with very frequent valve change attendances to be masked by long valve life individuals[3,7].

Recent research has largely relied upon retrospective analysis of hospital records[3,6,8] or has not specified how data was collected[7,12-14] and whether all data was analysed. Consistent data collection of consecutive patients in clinical practice is essential, but challenging, as observed in a study where 12% of valve replacements had no reason for exchange documented[6].

The differences in methodology and service models in previous studies outlined above require certain provisos when we compare our findings of valve life. Our overall (whole cohort) mean valve lifespan of 102 days (median 75, range 1-518) represents 3.66 valve changes per year. We anticipated reduced mean and median valve lifespan compared to previous studies not reporting on: a) self-change valves[6-7,14] as exdwelling valves have reported shorter lifespan[3] or b) pre-emptive valve changes before leakage occurs[7,12,14]. Despite our wide-ranging prophylactic and patient-initiated hospital changes (21.32% of attendances) where the valve was not leaking and also patient self-changes (17% of total valves used) our results compare favourably to previous large-scale studies. Kress et al[7] reported a mean of 108 days (median 74) whilst excluding all length change, TEP related and extrusions), and median only report by Petersen et al[6] of 70 days (excluded medical files incomplete/missing, removed for research purposes, rarely used valves, if immediate sizing error noted). Lewin et al[3] included both exdwelling valves and patient requested pre-emptive valve changes reported means of 86 days (median 61; range 1-816 days) but with several data exclusions (early oedema related, once recurrence confirmed, fitted at other units, removed for TEP injection). Studies have reported much longer valve duration which may potentially relate to methodological differences. A small-scale study[15] noted a mean of 207 days (median 222) but patients were recruited via a previous study and consequently not consecutive and were all more than 3-months post-surgery and without TEP problems. Two studies that did not include how data was collected[13-14] reported means of 17 months (range 1-36 months) and 16 months (range 1-42 months) respectively. Given the reported absence of intact details of SVR interventions in medical notes on retrospective analysis[6] the lack of transparency could be potentially relevant.

Further discussion is warranted around applying our findings on attendance frequency to clinical practice. Although our overall mean was 3.66 valve changes per year we found large inter and intra individual variation. The upper range of 31 total valve changes over the 36-month study period, together with the finding that interventions occurred at irregular intervals, offers a different perspective to how this may impact patients in terms of time, cost and planning travel to the unit and for those who commission SVR troubleshooting appointments.

A further key finding was that no definite patient profile emerged that predicted those at risk of more frequent interventions. The only variables to approach significance regarding more frequent valve changes were N stage and pre-operative CRT ($p = <0.066$ and <0.062) i.e. more extensive cancer and salvage laryngectomy after CRT showed a trend towards more frequent valve changes. Previous studies reported similarly that valve lifespan is unrelated to extent of surgery[3,6,14] but our findings contradict investigations reporting shortened valve life is significantly related to salvage procedure[6] or more specifically salvage post CRT compared to RT alone[8]. The effect of radiotherapy can be difficult to investigate statistically due to the infrequency of non-irradiation[6]. However, Lewin et al's[3] large cohort showed valve life was significantly reduced by RT although the authors questioned whether the short reduction (7 days) had clinical relevance.

Analysis of patient SVR attendance patterns i.e. the first 12-months post SVR compared to subsequent years and urgent vs elective appointments have not previously been reported in the literature. Our findings demonstrated that during the first year most patients should expect to attend every 5 weeks with a mean 42 days, median 36 days, but the wide range (0-115 days) suggests visits may be spaced unevenly. This contrasts to significantly less frequent attendance in our longer-standing patients who required an intervention every 109.96 days (mean) with the median and range (83 and 1-518 days respectively) again indicating continuing unpredictability with wide variation even when SVR is well-established. Furthermore, patients should expect urgent i.e. unplanned appointments in the first 12-months given our finding that just 1.77% of attendances in this period were elective compared to 26% in the group with established SVR.

When considering the reasons patients presented for SVR troubleshooting, central leakage through the valve was the key reason for valve change in both new and existing groups. The new users next most frequent reasons for change were the valve being too long or displacing accidentally. For the existing group it related to self-change or prophylactic change at hospital indicating that with time TEP oedema had stabilised, pre-emptive attendances could be initiated, and patients had begun to self-change in their own home. Peripheral leak accounted for 10% of attendances in established patients and less than 5% in the first year of SVR, similar to previous studies where it was reported as a reason for change in 9%[6] and 13%[16] of cohorts. We found 10 of our cohort of 99 experienced peripheral leak on more than one occasion and our data indicated a pattern of frequent changes for this type of leakage but once a solution was found they had longer gaps between their attendances. This suggests the modified flange valves typically employed to manage peripheral leak were successfully managing the issue. This database was not designed to investigate treatment outcomes, but more detailed investigation of this issue is planned in a subsequent paper.

A final, crucial factor to consider when reporting valve life relates to how quickly patients present for assistance, but factors motivating rapid or tardy attendance are poorly understood. One study stated patients appeared tolerant of minor leaks and reluctant for valve changes[14], another that some discontinued SVR due to socioeconomic necessity[13]. Neither stipulated the costs/travel involved. A recent investigation reported a significant correlation between longer driving time to access SVR troubleshooting and longer valve lifespan despite a median travel time of only 26 minutes in their cohort[6]. Petersen et al[6] recommended further research but conjectured delaying visits due to “travel burden” could be a factor in longer valve lifespans reported in an Australian study[15] where larger distances are inherent in the country’s healthcare delivery. Petersen et al[6] also proposed socio-economic burden may explain exceedingly long valve life noted in some studies[13-14] compared to services where patients are fully reimbursed.

Initiating studies of patient perspectives is warranted as cost, access to public transport, availability of appointments at peak/off-peak traffic times or different socioeconomic populations in more outlying areas may be more relevant in influencing patient promptness in accessing assistance than concern about time in the car. Little is known about the morbidity of SVR due to aspiration pneumonia or hospitalisation due to lack of provision or patients delaying assistance. A survey of English SVR units[5] reported one-third of respondents expressed dissatisfaction with their unit’s provision. Although this was solely from the perspective of SLT’s the impetus for this research arose from the national patient support group raising concerns about urgent SVR service provision. Patients need transparency about how their unit will support them when they require urgent SVR assistance in order to make an informed choice about accepting the commitments unique to this form of communication rehabilitation.

Our investigation was conducted in a fee-free healthcare system with free public transport to hospital for those aged 65+ years or on low income and hospital transport for those with mobility issues. Furthermore, the service model includes urgent and elective appointments pre-booked via telephone including later slots to allow travel from further afield and extra capacity is built in to account for variation in demand .We find patients tend to limit themselves to the weekday service and avoid the limited provision at weekends/bank holidays by nurses and medical staff.

The final research aims related to staffing resources and costs of consumables (Table 7). The mean cost per annum was calculated for this study as a unit that can modify valves in-house plus an additional calculation that can be used by units that would need to purchase factory modified valves. Cost comparisons with other units are not possible as this is the first comprehensive study. However, this provides an indication of the cost per year for a caseload of approximately one hundred patients with this specified service delivery model. Provox Activalves (£1,136 plus VAT per unit) which have enhanced valve life were not used during the study period but have since been initiated for a limited number of patients. Petersen et al[6] reported over 25% of patients fitted with this prosthesis subsequently developed TEP tract hypertrophy/infection. They suggested short device life may be a sign of this co-morbidity. The frequent changers in our study did not appear to have this type of issue. Lewin et al[3] reported Activalves had the greatest longevity but queried whether they may be less accessible to patients (USA based) due to the expense. More research is required to determine the cost/attendance reduction benefits and the issue of TEP complications.

In terms of staffing resource 802 SLT appointments (mean of 267 per annum) were needed with 21.3% being pre-booked to pre-empt leakage. The benefits of planning transport and reducing the risk of aspiration pneumonia for identified patients with this protocol do not seem to reduce mean valve lifespan when compared to similar units[3,6-7]. The appointments we provided exceeded those utilised, and we conclude this practice is warranted due to our finding that patients require urgent appointments in an irregular and unpredictable pattern. The exact length of appointments was not recorded but can be 1-2 hours for complex cases (30 minutes is allocated). Future investigation is needed to examine the exact resource requirement and should include aspects not included in this study e.g. in-patient SLT, other SVR and stoma products, and non-SVR communication and swallowing therapy appointments.

Since this study was conducted several key advantages of our unit's model of service delivery have assisted us in managing valve changes during the Covid-17 pandemic. The pre-booking system allows patients to wait outside with staff ready to escort them into a special room where this aerosol generating procedure can be managed more safely. Furthermore, the prophylactic valve changes permit patients to plan journeys and thus avoid using public transport. Lastly, as one in five valve changes take place within the patient's home the risk of patients or staff contracting the virus is reduced for a significant proportion of the caseload. Further research is needed to ascertain how and whether more patients can learn to self-change their voice prosthesis.

Conclusion

This is the first comprehensive data concerning the mean, median and range of valve changes patients can expect in the first year of SVR in relation to subsequent years. Our findings suggest that patients should be aware that attendances will be more frequent in the first 12-months but unpredictability of appointments is the norm and likely to persist indefinitely. This will allow them to judge if the enhanced communication afforded by SVR warrants this commitment. Our model of service delivery aims to offset this attendance burden via prophylactic valve changes and self-change options whenever appropriate. Despite this practice our mean/median valve lifespans appear comparable to similar units with no/less comprehensive employment of these options. Cost considerations during the current Covid-19 pandemic take lower priority given valve changes involve risk to patients and staff, but planned attendance is easier to manage and self-change at home is safest for all parties. Further studies should investigate how protocols of valve selection and service delivery influence patient satisfaction and behaviour in seeking prompt assistance. Studies also need to include risk management as delays in valve changes can result in aspiration pneumonia with the additional new threat of managing issues relating to Covid-19.

Summary

- Larger scale studies have demonstrated median valve lifespan of 61-74 days
- Information about the number and type of attendances for SVR is currently limited

This paper provides the following new information:

- patients can expect unpredictably spaced, unplanned hospital attendance for SVR that will be more frequent in the first 12 months
- no profile predicts those at risk of more frequent attendance
- units should design troubleshooting services around unpredictability of patients presenting for assistance
- incorporating prophylactic valve changes and self-changes at home did not reduce median valve lifespans compared to similar overseas units not offering these options
- mean valve costs per month at a regional UK centre

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Ethical Standards

The South East Scotland Research Ethics Service advised that National Health Service ethical review to conduct this study was not required as this study involves NHS staff and is an audit of current or past practice concerning a healthcare issue. The Caldicott Guardian at NHS Lothian provided approval for data analysis and submission for publication which included data management recommendations. Informed Consent was not required as the South East Scotland Research Ethics Service advised this is an audit of current or past practice concerning a healthcare issue and is not classed as a research study

References

1. Clarke, P, Radford, K, Coffey, M, Stewart, M. Speech and swallow rehabilitation in head and neck cancer: United Kingdom National Multidisciplinary Guidelines. *J Laryngol Otol* 2016; **130**: S176-S180

2. Royal College of Speech and Language Therapists, UK. Prosthetic Surgical Voice Restoration (SVR): The role of the speech and language therapist. *Policy Statement* 2010

3. Lewin, JS, Baumgart, LM, Barrow, MP, Hutcheson, KA. Device life of the tracheoesophageal voice prosthesis revisited. *JAMA Otolaryngol* 2017; **143**: 65-71

4. Elliot, A. Prosthetic Voice Rehabilitation Following Laryngectomy: It’s the Archer Not the Arrow. *JAMA Otolaryngol* 2017; **1**: 72

5. Bradley, PJ, Counter, P, Hurren, A, Cocks, HC. Provision of surgical voice restoration in England: Questionnaire survey of speech and language therapists. *J Laryngol Otol;* 2013; **127**: 760-767

6. Petersen, JF, Lansaat, L, Timmermans, AJ, van der Noort, V, Hilgers, FJM, van den Brekel, MWM. Postlaryngectomy prosthetic voice rehabilitation outcomes in a consecutive cohort of 232 patients over a 13-year period. *Head Neck- J Sci Spec* 2019; **41**: 623-631

7. Kress, P, Schäfer, P, Schwerdtfeger, FP, Rösler, S. Are modern voice prostheses better? A lifetime comparison of 749 voice prostheses. *Eur Arch Oto-Rhino-L* 2014; **271**: 133-140

8. Starmer, HM, Ishman, SL, Flint, PW, Bhatti, NI, Richmon, J, Koch, W *et al*. Complications that affect postlaryngectomy voice restoration: Primary surgery vs salvage surgery. *Arch Otolaryngol* 2009; **135**: 1165-1169

9. Owen, S, Paleri, P. Laryngectomy rehabilitation in the United Kingdom. *Curr Opin Otolaryngo* 2013; **21**:186-191

10. Miller, A. A laryngectomy consumables audit. *Bulletin of the Royal Language of Speech and Language Therapists* 2010; (May): 16-17

11. Chakravaty, PD, McMurran, AEL, Banigo, A, Shakeel, M, Ah-See, KW. Primary versus secondary tracheoesophageal puncture; Systematic review and meta-analysis. *J Laryngol Otol* 2018; **132**:14-21

12. Mayo-Yáñez, MI, Cabo-Varela, L, Dovalo-Carballo, C, Calvo-Henríquez, A, Martínez-Morán, A, Herranz González-Botas, JH. Provox 2® and Provox Vega® influential factors and duration. *Eur Arch Oto-Rhino-L* 2018*;* **275**: 1827-1830

13. Yenigun, A, Eren, SB, Ozkul, MH, Tugrul, S, Meric, A. Factors influencing the longevity and replacement frequency of provox voice prostheses. *Singap Med J* 2015; **56**: 632-636

14. Krishnamurthy, A, Khwajamohiuddin, S. Analysis of Factors Affecting the Longevity of Voice Prosthesis Following Total Laryngectomy with a Review of Literature. *Indian J Surg Oncol* 2018; **9**: 39-45

15. Hancock, K L, N. R. Lawson, NR, Ward, EC. Device life of the Provox Vega voice prosthesis. *Eur Arch Oto-Rhino-L* 2013; **270**: 1447-1453

16. Op de Coul, BMR, Hilgers, FJM, Balm, AJM, Tan, IB, van den Hoogen, FJA, van Tinteren, H. A decade of postlaryngectomy vocal rehabilitation in 318 patients. *Arch Otolaryngol* 2000; **126:** 1320-1328

Tables

Table 1 Database Fields

Valve Fields	**Biographical Fields**
Product Type In- vs exdwelling	Gender
Length	Age at surgery

In house[1] and Factory[2] modifications	Date of surgery
Date fitted	Disease Site
Date removed	TNM classification
Number and date dispensed (if self-change)	Type of Surgery: Total Laryngectomy (TL), Total Laryngectomy + pectoralis major repair (TL + PM), Pharyngolaryngectomy with free flap repair (PL), Partial Pharyngolaryngectomy + free flap patch repair (PPL), Total laryngectomy and base of tongue reconstruction (TL + BOT)
Reason for removal (1st,2nd,3rd): prophylactic (SLT booked), resize too long, resize too short accidental dislodgment, central leak, peripheral leak, patient request (not leaking), voice issues, Other (free text)	Primary/Salvage surgery
	Radiotherapy (pre/post-surgical)
	Chemotherapy (pre/post-surgical)
	Primary/Secondary TEP
	Date of death

1. *Additional large oesophageal flange glued to the existing valve flange or an additional large flange on the tracheal side either loose or glued*
2. *Provox Xtraflange*

Table 2: Gender distribution and age at surgery (mean years, SD) for subgroups and overall.

Variable	Existing n = 80	New n = 19	Overall n = 99
Gender	F: 17 M: 63	F: 5 M: 14	F: 22 M: 77
Age at time of surgery (years)	F: 58.9, SD 13.8 M: 61.1, SD 10.4	F: 66.4, SD 3.5 M: 62.4, SD 8.3	F: 60.6, SD 12.64 M: 61.4, SD 10.00

F female, M male, SD standard deviation.

Table 3: Summary medical characteristics of participants.

Variable	Existing		New		Overall	
	N	% of N	N	% of N	N	% of N
T stage	n71		n18		n89	
1	4	6	1	6	5	6
2	18	25	2	11	20	22
3	30	42	8	44	38	43

4	19	27	7	39	26	29
N stage	n70		n18		n88	
0	1	1	0	0	1	1
N+	37	53	9	50	46	52
NO	32	46	9	50	41	47
Primary vs Salvage	n80		n19		n99	
Primary operation	50	62	6	32	56	57
Salvage operation	30	38	13	68	43	43
Tumour site	n77		n19		n96	
1) Glottis	26	34	4	21	30	31
2) Hypopharynx,	8	10	2	11	10	10
3) Nasopharynx,	0	0	1	5	1	1
4) Sub-glottis,	2	3	0	0	2	2
5) Supra-glottis,	20	26	8	42	28	29
6) Trans-glottis	21	27	4	21	25	26
Surgery type	n80		n19		n99	
1) Pharyngo-laryngectomy	6	8	1	5	7	7
2) PPL,	3	4	1	5	4	4
3) Total Laryng.	65	81	17	89	82	83
4) Total Laryng & pec major,	5	6	0	0	5	5
5) Total Laryng & BOT	1	1	0	0	1	1
Number who received Chemoradiotherapy (CRT) or Radiotherapy (RT)						
Pre-op CRT	8		1		9	
Pre-op RT	24		10		34	
Post-op CRT	11		1		12	
Post-op RT	26		5		31	

n = number of cases in group for which data was available

Table 4: Primary reasons for change across all procedures during duration of study for the existing and new groups separately and cohort overall.

Reason for change	Existing group (n 80)	Rank order	Existing group %age	New group (n 19)	Rank order	New group %age	whole cohort (n 99)	whole cohort % all reasons	whole cohort as % overall without self-changes

accidental	23	7	2.88	15	3	8.67	38	3.91	4.72
central leak	286	1	35.88	91	1	52.6	387	39.79	48.26
peripheral leak	69	4	8.65	10	5	5.78	79	8.14	9.86
too long	32	5	4.01	28	2	16.18	60	6.18	7.47
too short	12	9=	1.50	3	9	1.73	15	1.54	1.86
voice	21	8	2.63	4	7=	2.31	25	2.57	3.10
other	25	6	3.36	12	4	6.93	37	3.81	4.60
patient request	12	9=	1.50	1	10	0.57	13	1.34	1.61
prophylactic	153	3	19.19	5	6	2.89	158	16.28	19.69
self-change	164	2	20.57	4	7=	2.31	168	17.31	-
Total with self-changes	797		100	173		100	970	100	-
Total without self-changes	633		-	169		-	802	-	100

Figures represent absolute numbers as well as total for each reason as a percentage of all changes. N = number of patients to whom procedures refer.

Table 5 Reasons for valve changes during first 12 months after operation for the prospectively followed group (n 19).

Reasons for valve changes first year	n for all changes in first year	Rank order	% of all changes
accidental	12	3	10.2
central leak	58	1	49.1

other	10	4	8.5
patient request	1	9	0.8
peripheral leak	5	5	4.2
prophylactic	2	7=	1.7
too long	25	2	21.2
too short	2	7=	1.7
voice	3	6	2.5
self-change	0	10	0
Total changes	118		100

Table 6 raw totals for different valves by groups and as percentage of all valves per group and for the whole cohort.

Valve type	total all valves existing		total all valves new		total valves whole cohort	
Indwelling valves	N	%	N	%	N	%
Blom Singer 16	219	27.48	82	47.40	301	31.03
Blom Singer Classic 20	47	5.90	2	1.16	49	5.05
Dual Valve	23	2.89	3	1.73	26	2.68
Provox Vega 16	54	6.78	13	7.51	67	6.91
Provox Vega 20	15	1.88	0	0	15	1.55
Provox Vega 22.5	4	0.5	0	0	4	0.41
Blom Singer Advantage 20	2	0.25	0	0	2	0.21
Ex-dwelling valves						
Blom Singer Duckbill	152	19.07	23	13.29	175	18.04
Blom Singer Lowpressure 16	113	14.18	18	10.41	131	13.51
Provox NID	168	21.08	32	18.50	200	20.62
Total all valves	797	100	173	100	970	100

Table 7 Total expenditure in relation to valve type and other consumables

Valve type	total valves whole cohort		Cost to unit	Cost to units that cannot in-house customise
Indwelling valves	N	%		
Blom Singer 16	301	31.03	@ £168 x 301 = £50,568	@ £252 x 155 LEF = £39,060 @ £168 x 146 = £24,528 Total £63,588
Blom Singer Classic 20	49	5.05	@ £172 x 49 =£8,428	@ £252 x 49 = £12,348

Dual Valve	26	2.68	@ £388 x 26 = £10,088	
Provox Vega 16	67	6.91	@ £159.65 x 67 = £10,696.55	
Provox Vega 20	15	1.55	@ £159.65 x 15 =3 £2,394.75	
Provox Vega 22.5	4	0.41	@ £159.65 x 4 = £638.60	
Blom Singer Advantage 20	2	0.21	@ £326 x 2 = £652	
Total indwelling	444	47.84	£83,465.90 (with VAT £100,159.08)	£100,405.90 (£120,487.08 with VAT)
Exdwelling valves				
Blom Singer Duckbill	175	18.04	@ £72 x 175 =£12,600	
Blom Singer Lowpressure 16	131	13.51	@ £92 x 131= £12,052	
Provox NID	200	20.62	@ £84.25 x 200 = £16,850	
Total Exdwelling	506	52.16	£41,502 (with VAT = £49,802.40)	£41,502 (£49,802.40 with VAT)
Total all valves	970	100	£124,967.90 (£149,961.48 with VAT)	£145,098.85 (£174,118.62 with VAT)
Provox Xtraflange	11		@11x £30.39 = £334.29 (£401.15 with VAT)	@ £30.39 x 105 = £3,190.95 (£3,829.14 with VAT)
Custom in-house Modification Silicone sheet Adhesive	 6 2		@ £40 x 6 = £240 @ £60 x 2 = £120 (£432 with VAT)	
Total all consumables			£125,662.19 (£150,794.63 with VAT)	£145,098.85 (£174,118.62 with VAT)