

Feasibility of integrating videofluoroscopy in a large head and neck cancer (HNC) trial



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Introduction

Reducing dysphagia is an important endpoint in HNC trials. Most rely on patient-reported swallowing outcome measures (PROMs) which poorly correlate with swallow impairment and aspiration. The 'gold standard' impairment test is videofluoroscopy (VF), but it has rarely been integrated into co-operative trials. PATHOS¹ is a multi-centre phase III trial investigating de-intensification of adjuvant treatment for HPV-positive oropharyngeal squamous cell carcinoma (OPSCC) following transoral surgery. It includes a multi-dimensional panel of swallowing measures (PROMs, clinical tests and VF) as endpoint measures. This study evaluated the feasibility of integrating VF in a co-operative group setting in the UK.

Methods

A pre-trial feasibility questionnaire recorded the range of VF practices, informing an evidence-based VF protocol and analysis plan. VFs were limited to three time points (pre-surgery, pre-adjuvant radiotherapy and 12 months post-treatment). Blinded central VF review by Speech and Language Pathologists (SLPs) was planned, using three validated measures, recording swallowing pathophysiology, efficiency and safety: MBS Impairment Scale (MBSImP™©); Dynamic Imaging Grade of Swallowing Toxicity (DIGEST); and Penetration-aspiration Scale. An interim analysis was conducted on 40 randomly selected VFs at 12 months post-treatment.

Results

28/31 centres submitted 600 VFs. Completion rate: 51% pre-surgery; 72% pre-radiotherapy; 70% at 12 months. Reasons for non-submission; insufficient time and capacity. 99.5% of bolus trials were completed. 80% had functional swallows (DIGEST grade 0-1) with an excellent safety profile (figure 1). Two patients had penetration that was not ejected. Mean MBSImP™© scores for oral impairment were 4.9; SD 3.5; 95% CI 3.9-6.3; pharyngeal impairment 7.6; SD 2.9; 95% CI 7.4-9.4 (figure 2).

Figure 1 DIGEST VF scores

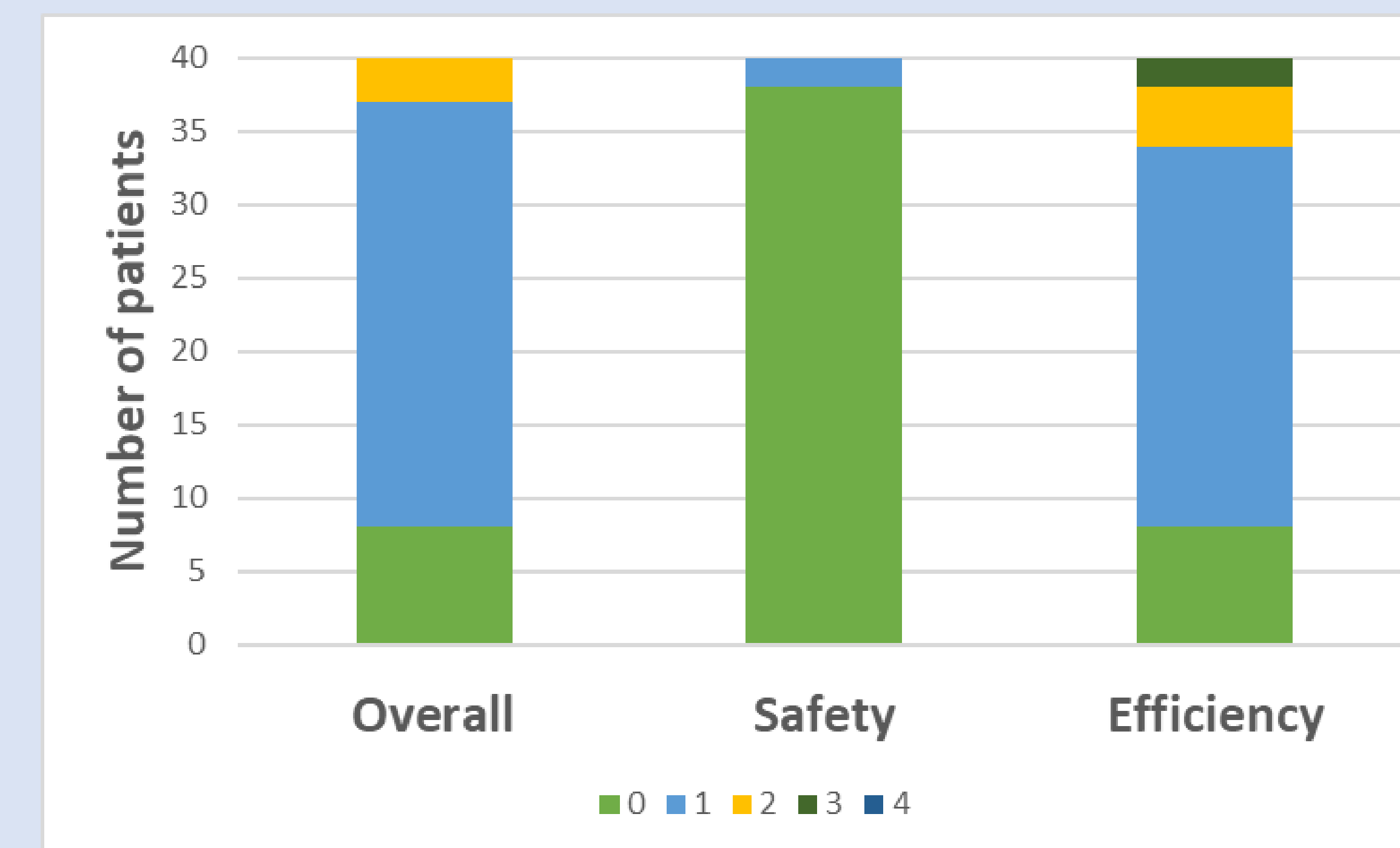
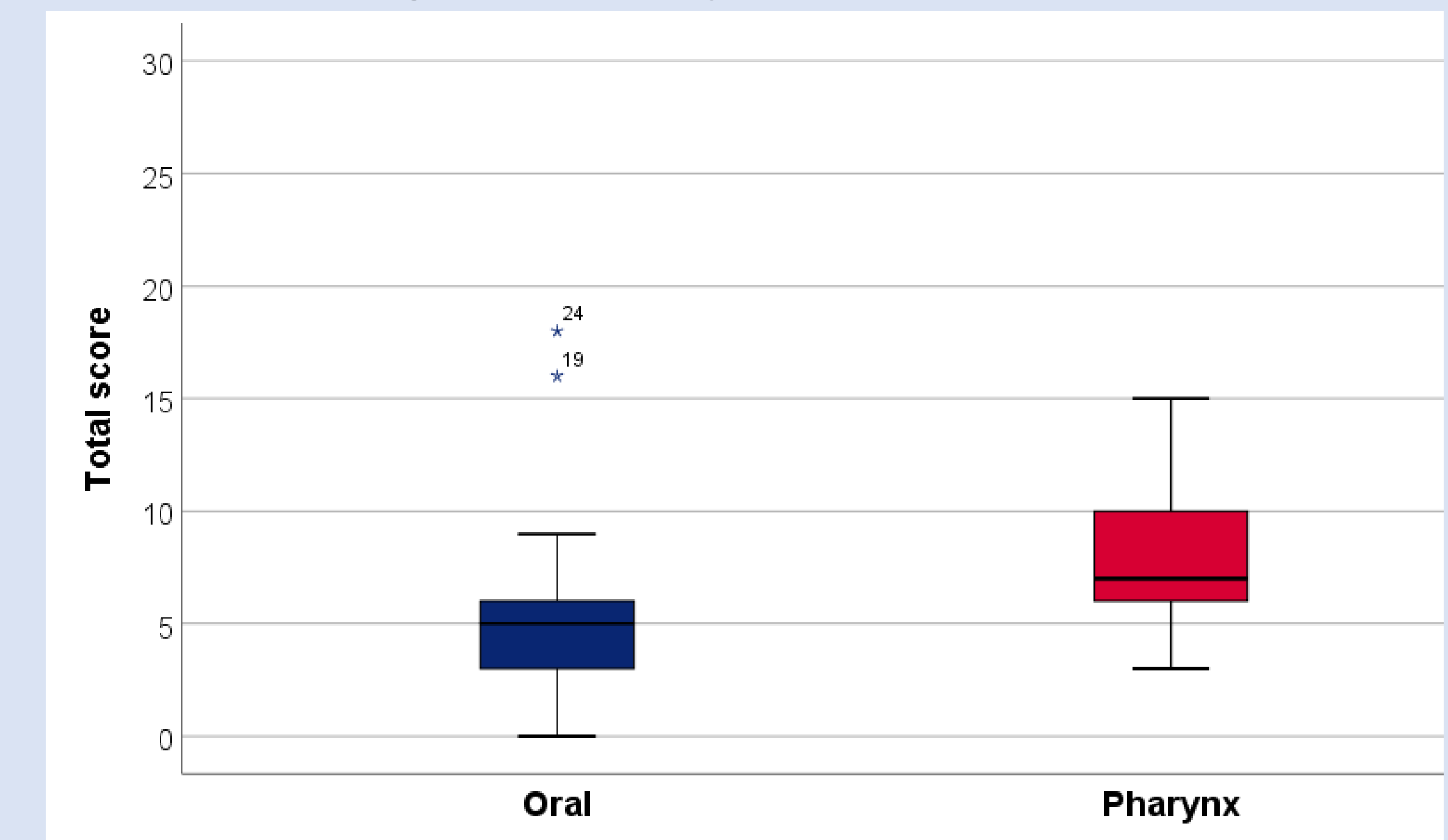


Figure 2 MBSImP™© scores



Conclusion

VF is feasible in a large cooperative group trial. Preliminary results suggest good safety and efficiency profiles and modest physiologic swallowing impairment at 12 months following surgery and adjuvant treatment for HPV-positive OPSCC. PATHOS will report on the effect of treatment de-intensification on long term swallowing function.

Reference

1. Owadally W et al PATHOS: a phase II/III trial of risk-stratified, reduced intensity adjuvant treatment in patients undergoing transoral surgery for Human papillomavirus (HPV) positive oropharyngeal cancer BMC Cancer 2015;15:602

