Plenary Session – Best Abstracts

Abstract Titles

The NeuroSAFE RCT Feasibility Study

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Introduction: Intra-operative Frozen Section (IFS) analysis during robot-assisted laparoscopic radical prostatectomy (RALP) is controversial. The NeuroSAFE technique (IFS of the prostate margin adjacent to the neuro-vascular bundles) has demonstrated improved rates of nerve-sparing (NS) whilst maintaining oncological safety in retrospective observational studies. NeuroSAFE has never, however, been evaluated by a Randomised Controlled Trial (RCT).

Methods: The NeuroSAFE PROOF Feasibility Study (NCT03317990) was designed to evaluate whether it is acceptable to men to be randomised to either NeuroSAFE RALP vs. standard RALP as part of a prospective clinical trial. Potent men (IIEF-25 >21) with organ-confined prostate cancer were eligible for recruitment.

Results: From May 2018 to December 2018 52 patients were approached at two UK regional centres. 51 men were recruited to the trial and 50 RALPs were performed as per random treatment allocation. We report the NS status of the 48 men treated at the UCLH site. Intervention arm (NeuroSAFE RALP) noted “any degree of NS” in 89.6% vs. 60% in the control arm (standard RALP). Intervention arm noted bilateral intrafascial NS RALP in 15 men (62.5%) vs. 8 men (33%) in the control arm.

Conclusions: NeuroSAFE PROOF Feasibility Study has demonstrated feasibility by achieving its recruitment outcome. This has permitted progress to the full scale, definitively powered, multi-site NeuroSAFE PROOF RCT, which is underway. We present this trial in progress with updates on the preliminary analysis of promising secondary outcomes (such as NS rates) from the feasibility study. Maturation of patient reported functional outcomes and oncological outcomes is awaited.