Technoleg Iechyd Cymru
Health Technology Wales

Topic Exploration Report

Topic explorations are designed to provide a high-level briefing on new topics submitted for consideration by Health Technology Wales. The main objectives of this report are to:

- Determine the quantity of evidence available for a technology of interest.
- Identify any gaps in the evidence.
- Inform decisions on topics that warrant fuller assessment by Health Technology Wales (HTW).

Topic exploration report number:	TER361
Topic:	RayPilot, a novel real-time electromagnetic tracking device, used during radiotherapy to treat prostate cancer.
Summary of findings:	Health Technology Wales researchers identified three observational studies on RayPilot, two of which were comparative. The studies varied in their design, the comparator used, and the radiotherapy treatment schedule. Based on the evidence identified, it is unclear whether the use of RayPilot alone leads to greater system benefits and improved outcomes when compared to standard practice in the UK. It is also uncertain whether RayPilot would be best used alongside fiducial markers and how RayPilot would fit into the current care pathway. We did not identify any studies evaluating the cost effectiveness of RayPilot.

Introduction and aims

By obtaining a more accurate location of the tumour, physicians could deliver a higher radiation dose in fewer fractions with tighter treatment margins. Stereotactic body radiation therapy (SBRT) uses higher dose fractions employed with tighter margins than conventional radiotherapy.

The RayPilot monitoring system provides real-time localisation of the prostate based on electro-magnetic detection of a transmitter, which is placed intra-urethrally by means of a dedicated catheter to identify anatomy and allow intra-fractional tracking. RayPilot is a non-ionizing non-interfering real-time positioning system that is removed after treatment. RayPilot is indicated for use with men who have been diagnosed with tumour stages T1, T2, T2a, T2b, T2c, T3 and T3a.

Health Technology Wales researchers searched for evidence on the clinical effectiveness, cost effectiveness and the safety of RayPilot when compared to the standard of care.

Evidence overview

Clinical effectiveness

Health Technology Wales researchers identified three observational studies investigating use of RayPilot during SBRT. Two of these studies were comparative: one compared RayPilot to no intrafraction motion management, and the other compared the localisation accuracy of RayPilot to another electromagnetic tracking system called Calypso.

It is unclear from the available evidence what is currently used to improve the localisation accuracy during SBRT. Two out of three studies used the RayPilot system alongside fiducial markers.

Observational studies

One prospective observational study of 13 people undergoing SBRT reported the real-time measurement of the transmitter displacement for each treatment fraction during SBRT (Panizza et al. 2022). The percentage of time that the prostate spent outside the 2 mm threshold (criterion for positional stability) in each of the three spatial directions during the setup, delivery, and total treatment with and without RayPilot was reported. Without RayPilot, the prostate would have been found outside the 2 mm tolerance in 8% of the total session treatment time compared to 7% with RayPilot. The time-to-treatment data for RayPilot was reported and compared to treatment without any without intrafraction motion management. It is unclear how the time-to-treatment data would compare to what is used in standard practice for SBRT.

One other prospective observational study of ten people compared the patient experience and the positional stability of RayPilot whilst using fiducial markers during SBRT (Braide et al. 2018). In this study, patients reported mild to moderate discomfort and impact on daily activities. As RayPilot was used alongside fiducial markers, it is unclear how patient reported outcomes would differ if fiducial markers were not used.

Panizza et al. (2022) did not report adverse events as an outcome, whereas Braide et al. (2018) recorded no substantial adverse events through their adverse event form.

One retrospective study (Vanhanen et al. 2018) compared the localisation accuracy of two electromagnetic tracking systems (RayPilot and Calypso) during moderate hypofractionation schedule of 20 fractions using fiducial marker based orthogonal kilovoltage (kV) imaging. The prostate localisation data for RayPilot was retrospectively gathered from a previous study investigating the effect of rectal retractor device (RR) on prostate intrafraction motion. The study

concluded that the localisation accuracy of the RayPilot system is not equivalent to kV imaging of fiducial markers and is not adequate for interfraction localisation of the prostate. The study recommended that RayPilot could be used for intrafractional motion tracking, but the initial localization should be made by some other means such as kV or cone beam computed tomography (CBCT) imaging of fiducial markers.

Guidelines

A 2019 NICE guideline which was amended in 2021 entitled, 'Prostate cancer: diagnosis and management' (NG131) (NICE 2019), covers the diagnosis and management of prostate cancer in secondary care, including information on the best way to diagnose and identify different stages of the disease, and how to manage adverse effects of treatment. The guideline makes no specific reference to RayPilot.

Areas of uncertainty

Based on limited clinical evidence found in this report, it is unclear whether the use of RayPilot alone (without fiducial markers) leads to greater system benefits and improved outcomes when compared to standard practice in the UK. Clinical evidence evaluating whether RayPilot would lead to better genitourinary (GU) and gastrointestinal (GI) toxicity outcomes and better patient quality of life was not identified.

It is unclear what the current standard of care is, what comparator would be most appropriate, and whether the evidence using fiducial markers alongside RayPilot is appropriate.

We did not identify economic evidence about RayPilot, including the cost effectiveness of RayPilot in relation to the UK health system, or the costs of RayPilot when compared to (or used alongside) standard care.

Literature search results

Health technology assessments and guidance
NICE. (2019). Prostate cancer: diagnosis and management NICE guideline [NG131]. Available at: https://www.nice.org.uk/guidance/ng131 [Accessed 6 May 2022].
Evidence reviews and economic evaluations
No evidence identified
Individual studies
Braide K, Lindencrona U, Welinder K, et al. (2018). Clinical feasibility and positional stability of an implanted wired transmitter in a novel electromagnetic positioning system for prostate cancer radiotherapy. Radiotherapy and Oncology. 128(2): 336-42. doi: https://doi.org/10.1016/j.radonc.2018.05.031 NICE. (2019). Prostate cancer: diagnosis and management NICE guideline [NG131]. Available at: https://www.nice.org.uk/guidance/ng131 [Accessed 6 May 2022]. Panizza D, Faccenda V, Lucchini R, et al. (2022). Intrafraction Prostate Motion Management During Dose-Escalated Linac-Based Stereotactic Body Radiation Therapy. Frontiers in Oncology. Available at: https://www.frontiersin.org/articles/10.3389/fonc.2022.883725/full Vanhanen A, Syrén H, Kapanen M. (2018). Localization accuracy of two electromagnetic tracking systems in prostate cancer radiotherapy: A comparison with fiducial marker based kilovoltage imaging. Physica Medica. 56: 10-8. doi: https://doi.org/10.1016/j.ejmp.2018.11.007
Ongoing research
No evidence identified

Date of search:	**May 2022**
Concepts used:	RayPilot, electromagnetic positioning system, intrafraction motion tracking, electromagnetic (EM) transmitter-based device, intrafraction motion management