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Title: Helica diathermy for the treatment of 11 patients with Recurrent Respiratory Papillomatosis

5 key points

1. To date there is no effective treatment modality for RRP.
2. Helica TC diathermy can be used for RRP of the larynx.
3. Helica TC shows promise as an alternative treatment for adult patients with RRP, particularly in refractory cases where other traditional methods have been used.
4. A prospective trial involving comparison of traditional methods and the Helica TC diathermy would further investigate the efficacy of this device and enable formal guidance to be established for the treatment of RRP.
5. As yet we do not know the mode of action of Helica TC on RRP, to be further investigated through experimental pathology techniques.

Main body 1500 words

Dear Editor, We would like to report a novel method of treatment for Recurrent Respiratory Papillomatosis (RRP) of the larynx.

RRP is a benign laryngeal neoplasm most commonly found in childhood. More than 70 types of human papillomavirus have been described with serotypes 6 and 11 generally associated with laryngeal disease affecting both sexes and ages. Respiratory papillomatous lesions are largely treated by excision using a variety of different surgical techniques e.g. cold steel, laser or by microdebrider. RRP is almost always benign, however it is common for patients to require repeat surgery for recurrence. For refractory cases some centres have combined their surgery with adjuvant treatments with intralesional chemotherapeutic agents e.g. Cidofovir injections, which have been shown to increase the inter-operative intervals.

The best method for surgical removal of these lesions remains the subject of ongoing debate. The Helica Thermal Coagulator (Helica TC, Helica Instruments Ltd., Riccarton, Edinburgh, UK) is an instrument that combines low-pressure helium gas with low-voltage (2-8 Watts) electrical power along a single insulated probe (Figure 1a and b). This method of diathermy was introduced into clinical practice in Scotland in 1993 and is widely used in gynaecology for the treatment of endometriosis. The device has been licensed in many countries for this purpose.

The Helica TC probe emits helium and the physical effects can be controlled by modifying the power of AC current to cauterise tissue to a depth of one cell thickness allowing great precision of diathermy. The amount of energy delivered to tissue is dependent on the distance from the probe to the tissue at a given power. The Helica TC beam is attracted to tissues with relatively high water content, which acts to limit collateral tissue damage. The flow of gas disperses blood and fluid from the tissue before impact, which allows the energy to be concentrated on bleeding vessels helping haemostasis (use in Otolaryngology). Due to these properties it was proposed that the Helica TC may be an ideal technique to eliminate RRP.

Ethical Consideration

Ethical approval awarded for the use of the Helica Thermal Coagulator in ENT for Benign Laryngology Surgery by the National Research Ethics Service, Essex 1 Research Ethics Committee. In addition the Clinical Novel Interventions department at Guy's and St Thomas' NHS Trust approved the use of Helica TC on the larynx as it was an existing machine in use at the trust with a variation of methods.

Methods

Patients with RRP de novo and/or unresponsive to conventional therapies were offered the opportunity to undertake Helica TC as a new treatment for their recurrent respiratory papillomas. An explanation of the technique was given along with an information sheet prior to formal consent.

Patients received a general anaesthetic and were positioned supine. A standard microlaryngoscopy was performed and with the aid of the Zeiss microscope the Helica TC probe was used, held in a non-touch technique 3-5 mm away from tissue as the energy is efficiently delivered in a non-touch mode.

Review took place routinely 8 weeks post-operatively and follow-up took place to establish resolution of RRP disease.

Results

11 patients approached between 2007-2015 agreed to participate.

Patient	Age at presentation (year)	Number of laser/cold steel procedures before helica (year)	Number of Helica TC procedures (year)	Number of laser/cold steel procedures after helica (year)	Follow up until discharge (year)	Complications? attributed to Helica TC
1	54 M	1 (2007)	1 (2007)	0	2010	None
2	40 M	4 (1997 x 2, 1998, 2007)	1 (2008)	4 (2008, 2009, 2010, 2012)	2013	None
3	44 M	0	1 (2012)	0	2013	None
4	36 M	3 (2004, 2005, 2009)	1 (2011)	0	2013	None
5	46 M	1 (2011)	1 (2012)	0	2014	None
6	46 (F)	1 (2014)	2 (2014, 2015)	0	2015 ongoing surveillance	None
7	34 M	10 (1998 x 2, 1999 x 2, 2000, 2001, 2003, 2005 x 2, 2008)	3 (2009, 2010, 2013)	0	2015	None
8	64 (F)	0	1 (2014)	0	2015 ongoing surveillance	None
9	30 (M)	6 (2008 x 2, 2010 x 2, 2011, 2013)	2 (2014)	0	2015 ongoing surveillance	None
10	8 (F)	0	1 (2012)	1 (2012)	2012	Referred to tertiary centre due to arytenoid web
11	1(F)	15	1	4	2015 ongoing surveillance	Referred to tertiary centre due to arytenoid web

Case 1

A male 54-year-old non-smoker presented with hoarseness in May 2007. Four months after receiving a microlaryngoscopy and cold steel removal of the RRP lesion on the anterior third of the right vocal fold, the lesion recurred. The Helica TC probe was used to eliminate the papillomatous lesion that now involved the anterior commissure, two thirds of anterior right vocal fold and the entire left vocal fold. The patient was followed up until August 2010 with no recurrence of the lesion.

Case 2

A male 40-year-old non-smoker had suffered with hoarseness since 1996 caused by laryngeal papillomas. The gentleman underwent (2 or 17 microlaryngoscopies, cold steel and laser ablation prior to Helica TC. Due to the refractory nature of the papilloma Helica TC was trialled to remove the papillomas. Post-Helica TC treatment his breathing improved and there was a report that he felt no pain compared to the laser treatment in July 2008. The gentleman required 4 further microlaryngoscopic

procedures with laser until the papillomas resolved and was discharged in July 2013 with no recurrence.

Case 3

A 44-year-old gentleman who had been dysphonic for months was seen in the voice clinic and right vocal fold papilloma was diagnosed and removed by cold steel in July 2012. In August 2012 Helica TC was used to treat this right vocal fold and by September 2012 there was no recurrence so was discharged to the care of the speech and language team for voice rehabilitation (Figure 2A and B).

Safety

The Helica TC device has approval by the SGS Certification Body for use in the EU and the products designed and manufactured by Helica Instruments Ltd are in accordance with the scope of a quality system which meets the requirements of ISO 13485:2003/ISO 9001:2008 and Medical Devices Directive – 93/42/EEC.

Discussion and future application

The Helica TC diathermy may be promising and should be considered as an alternative treatment for patients with RRP, particularly in refractory cases where other traditional methods have not controlled the disease.

The diathermy technology is being used with success in gynaecology and other areas of otolaryngology e.g. tonsillectomy and has been proved as safe. Two series looking at the use of Helica TC as a treatment modality for early stage endometriosis in 79 and 1060 patients respectively state that Helica TC has a complication rate of only 0.1%, this being testament to its safety (Nardo et al., 2005, Hill et al., 2006). No major complications occurred using the conventional non-cutting probe and no patient required conversion to laparotomy or blood transfusion.

Review of results following the use of laser for RRP has shown significant scarring over the years with no benefit on recurrence rates. There is still a search for an improved treatment of this disease and thus Helica TC is easy to use and the results of our pilot study suggest it may be an effective means of removing papillomas from the larynx in adults. We would advise a caution in the use of Helica TC in paediatric cases however as both paediatric cases with Helica TC treatment appeared to promote scarring and webbing. A prospective trial in adults involving comparison of traditional methods, i.e. laser/cold steel/microdebrider and the Helica TC diathermy would further investigate the efficacy of this device and enable formal guidance to be established for the treatment of RRP. Prior to the commencement of any such trial the size and shape of the Helica TC probe needs to be adjusted specifically for use in the larynx.

Conflict of interest

none

References

Figure 1A HTC probe, **B** HTC control box with variable wattage.

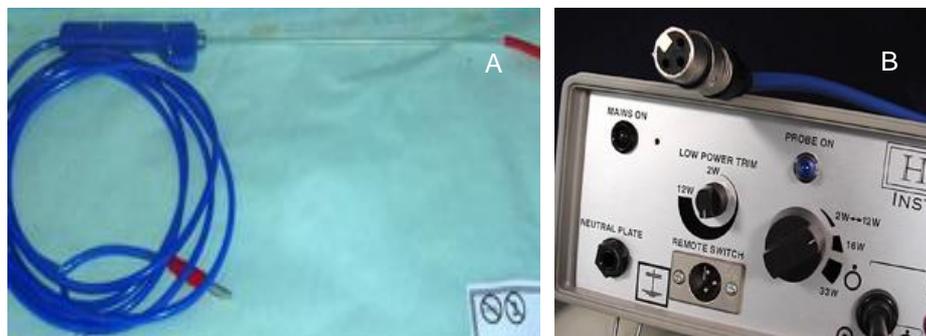


Figure 2A Pre-operative view under microlaryngoscopy of right vocal fold papilloma. **B** Peri-operative view under microlaryngoscopy of right vocal fold after treatment with HTC.



Patient 8: A Pre-operative photo, B perioperative photo, C 5 months post operative photograph
Histology: Benign squamous papilloma with fibrovascular connective tissue cores supporting acanthotic parakeratinised stratified squamous epithelium containing koilocyte like cells. Op 12th march 2014

Patient 9: A Pre-operative photo, B perioperative photo C 4 months post-operative photograph



Patient 11:

